



US009242077B2

(12) **United States Patent**
Wilson et al.

(10) **Patent No.:** **US 9,242,077 B2**
(45) **Date of Patent:** **Jan. 26, 2016**

(54) **DYNAMIC ADJUSTMENT TOOL FOR PROGRAMMING AN IMPLANTABLE VALVE**

(56) **References Cited**

(71) Applicant: **DePuy Synthes Products, LLC**,
Raynham, MA (US)
(72) Inventors: **Stephen Wilson**, North Easton, MA
(US); **Alyssa Trigger**, South Boston,
MA (US); **Brian Soares**, Norton, MA
(US)
(73) Assignee: **DePuy Synthes Products, Inc.**,
Raynham, MA (US)

U.S. PATENT DOCUMENTS

4,540,400	A *	9/1985	Hooven	604/9
5,643,194	A	7/1997	Negre	
7,921,571	B2	4/2011	Moureaux et al.	
8,038,641	B2	10/2011	Soares et al.	
8,241,240	B2	8/2012	Murphy	
2002/0022793	A1	2/2002	Bertrand et al.	
2005/0022403	A1	2/2005	Moskowitz et al.	
2005/0120571	A1	6/2005	Moskowitz et al.	

(Continued)

FOREIGN PATENT DOCUMENTS

EP	2316520	A1	5/2011
EP	2316522	A1	5/2011
FR	2858239	A1	4/2005

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 333 days.

(21) Appl. No.: **13/795,139**

(22) Filed: **Mar. 12, 2013**

(65) **Prior Publication Data**
US 2014/0276339 A1 Sep. 18, 2014

(51) **Int. Cl.**
F16K 37/00 (2006.01)
F16K 31/08 (2006.01)
A61M 27/00 (2006.01)

(52) **U.S. Cl.**
CPC **A61M 27/006** (2013.01); **F16K 31/08**
(2013.01); **F16K 31/088** (2013.01); **F16K**
37/0041 (2013.01); **A61M 2205/3515**
(2013.01); **A61M 2205/8287** (2013.01); **Y10T**
137/8225 (2015.04); **Y10T 137/8242** (2015.04)

(58) **Field of Classification Search**
CPC A61M 27/006; A61M 2205/3515;
A61M 2205/8287; F16K 31/088; F16K
37/0041; Y10T 137/8242; Y10T 137/8225
USPC 604/9, 891; 251/65, 129.06; 137/553,
137/554

See application file for complete search history.

OTHER PUBLICATIONS

European Search Report dated Oct. 10, 2014.

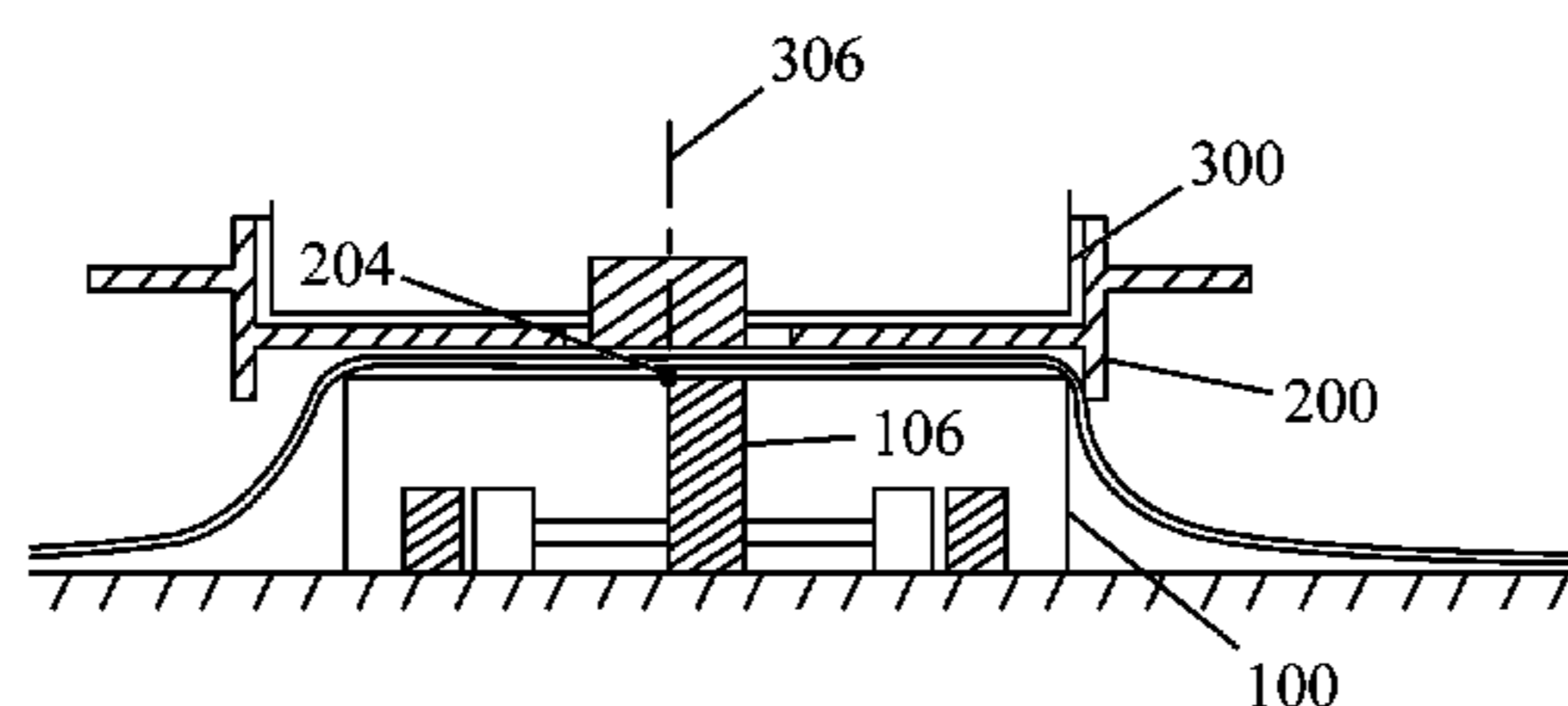
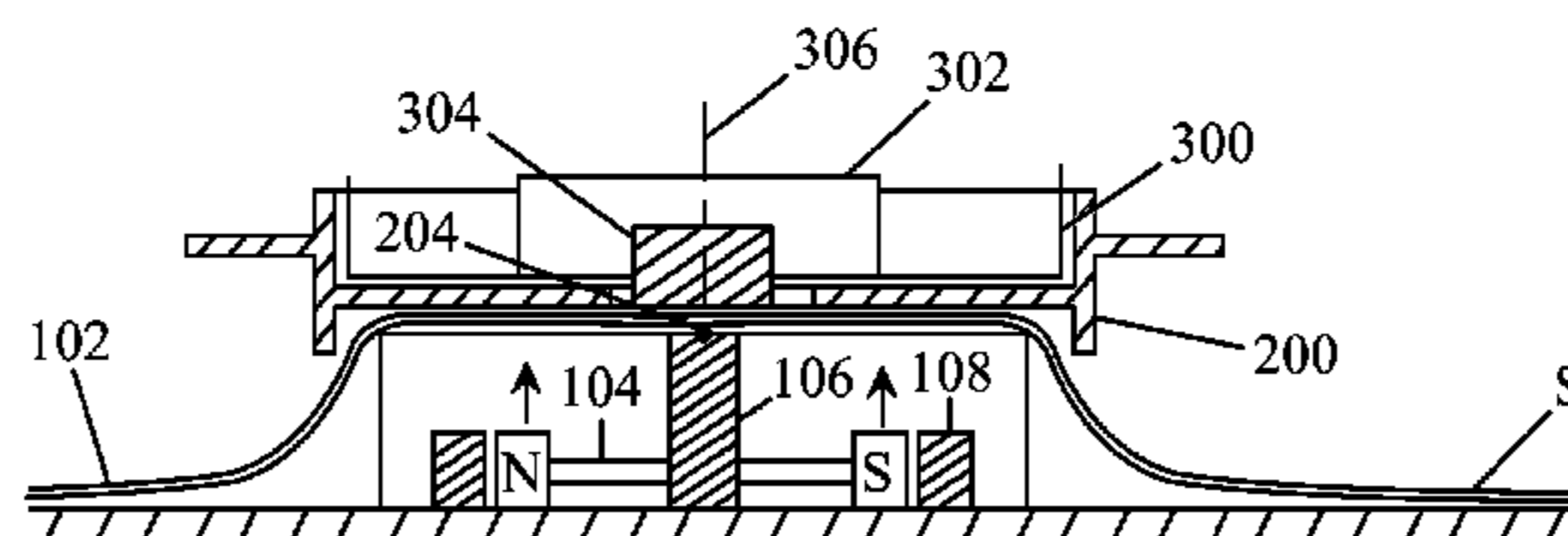
Primary Examiner — Atif Chaudry

(74) *Attorney, Agent, or Firm* — Troutman Sanders LLP

(57) **ABSTRACT**

A tool includes a locator having a center aligned with a rotor axis when disposed over the valve. The locator has a first dimension approximately perpendicular with the rotor axis. A wall of the locator forms a volume to allow an adjustor to be disposed therein. The adjustor fits within the wall and has a magnet having a magnetic axis to unlock the rotor. An adjustable outer wall has a first position dimension permitting the adjustor to rotate about the center of the locator and aligning the magnetic axis with the center. The adjustable outer wall has a second position dimension less than the first dimension and the first position dimension. The adjustor can move lateral, rotational, and orbital in the locator misaligning the magnetic axis with the center. Misaligning the magnetic and rotor axes unlocks the rotors and the magnet maintains the unlocked state even when the axes are misaligned.

15 Claims, 11 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

2011/0048539 A1 3/2011 Negre et al.
2011/0105991 A1 5/2011 Roth et al.

2011/0105992 A1 5/2011 Girardin et al.
2011/0105993 A1 5/2011 Girardin et al.
2011/0105994 A1 5/2011 Ginggen et al.
2014/0121586 A1 5/2014 Bertrand et al.

* cited by examiner

Fig. 1A

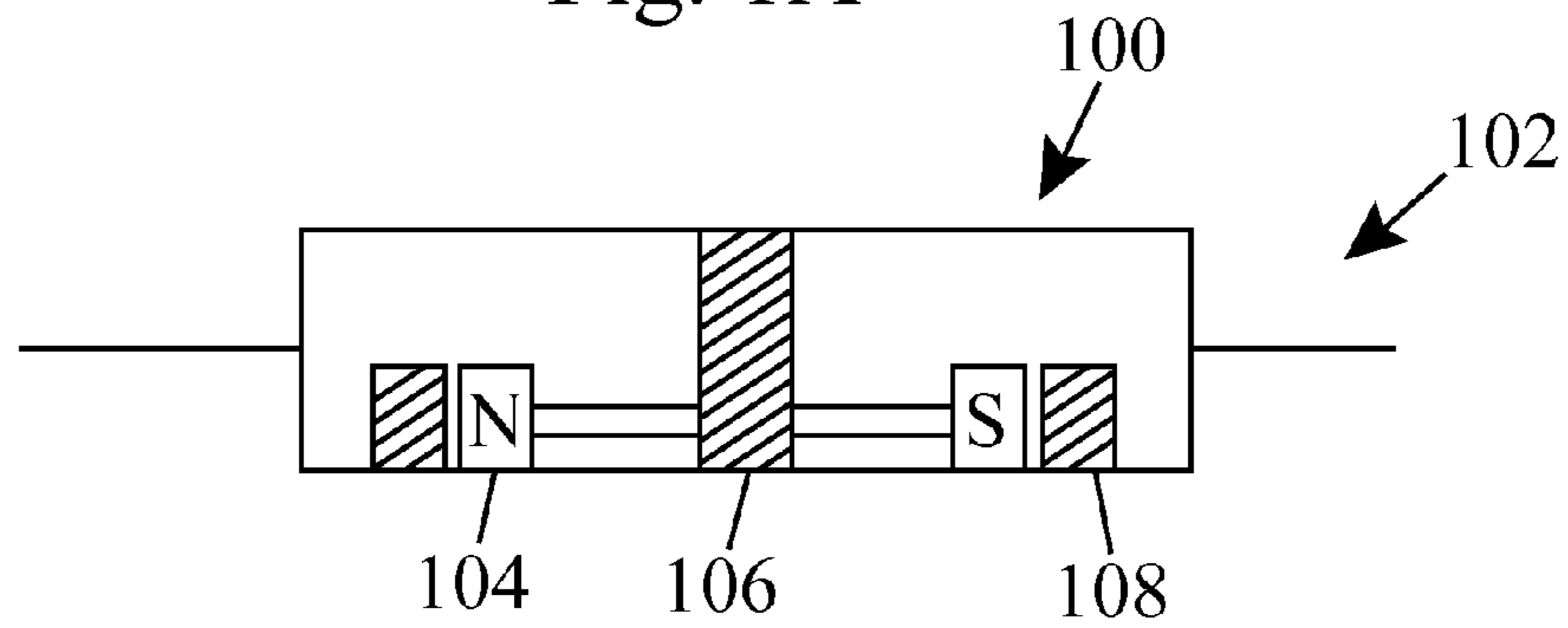


Fig. 1B

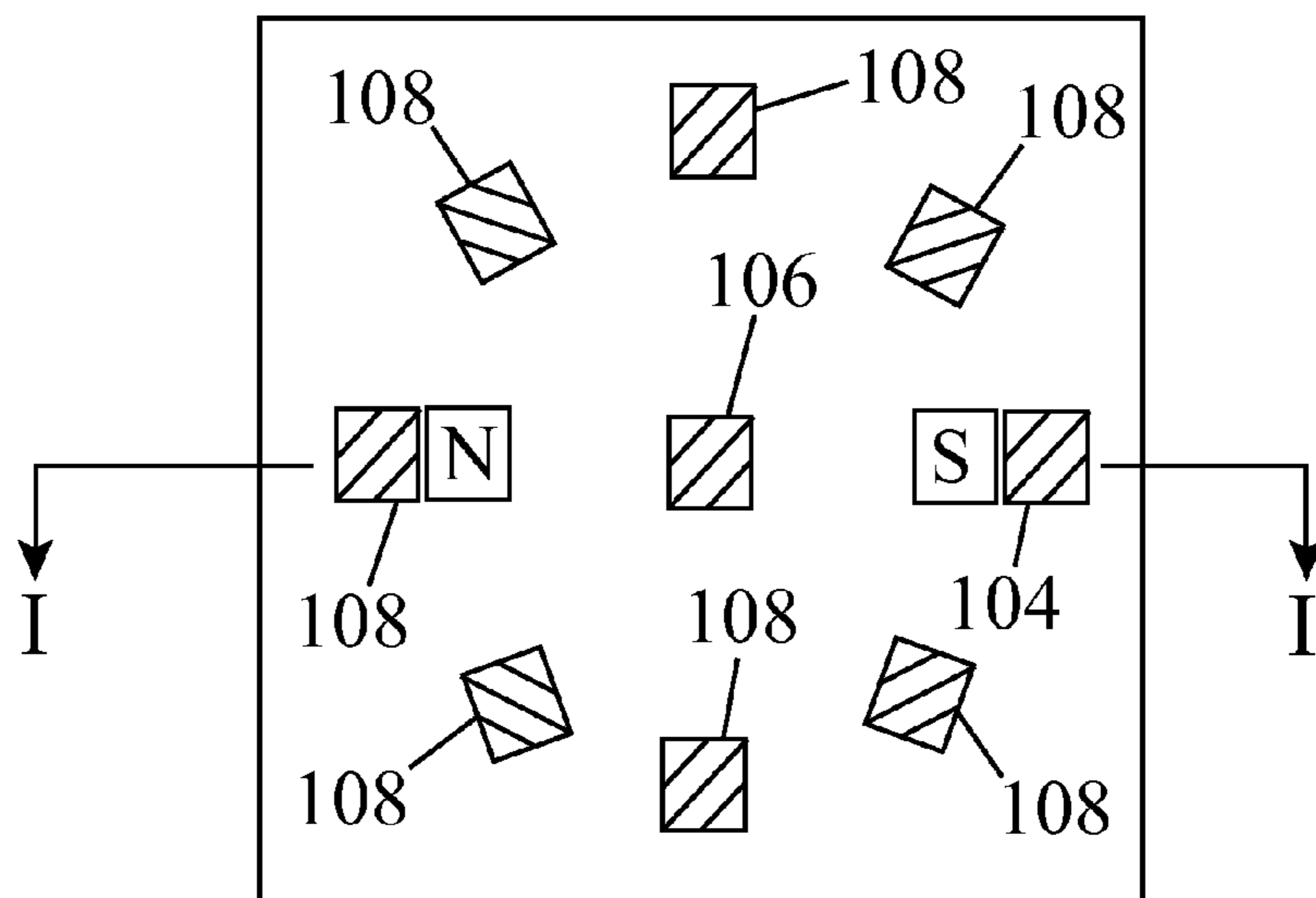


Fig. 1C

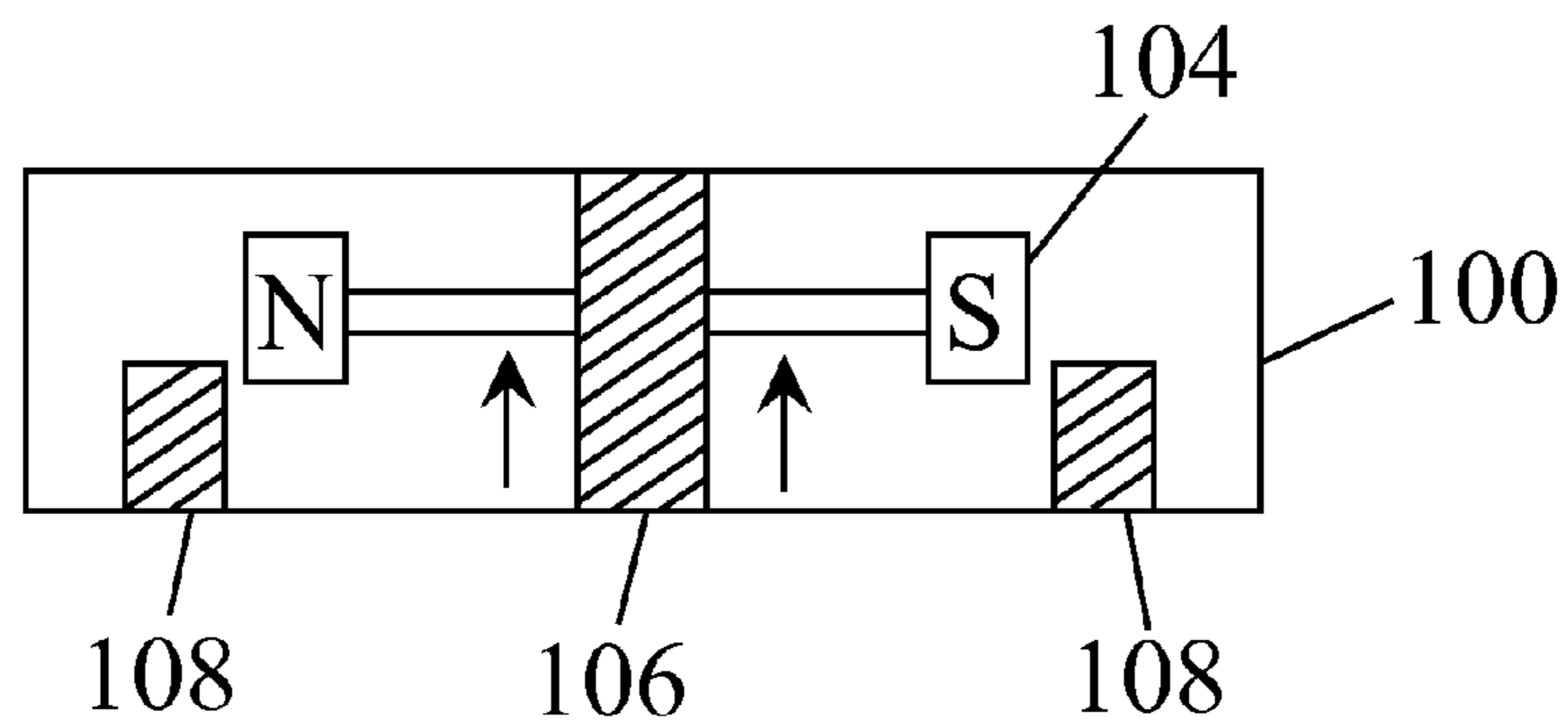


Fig. 2A

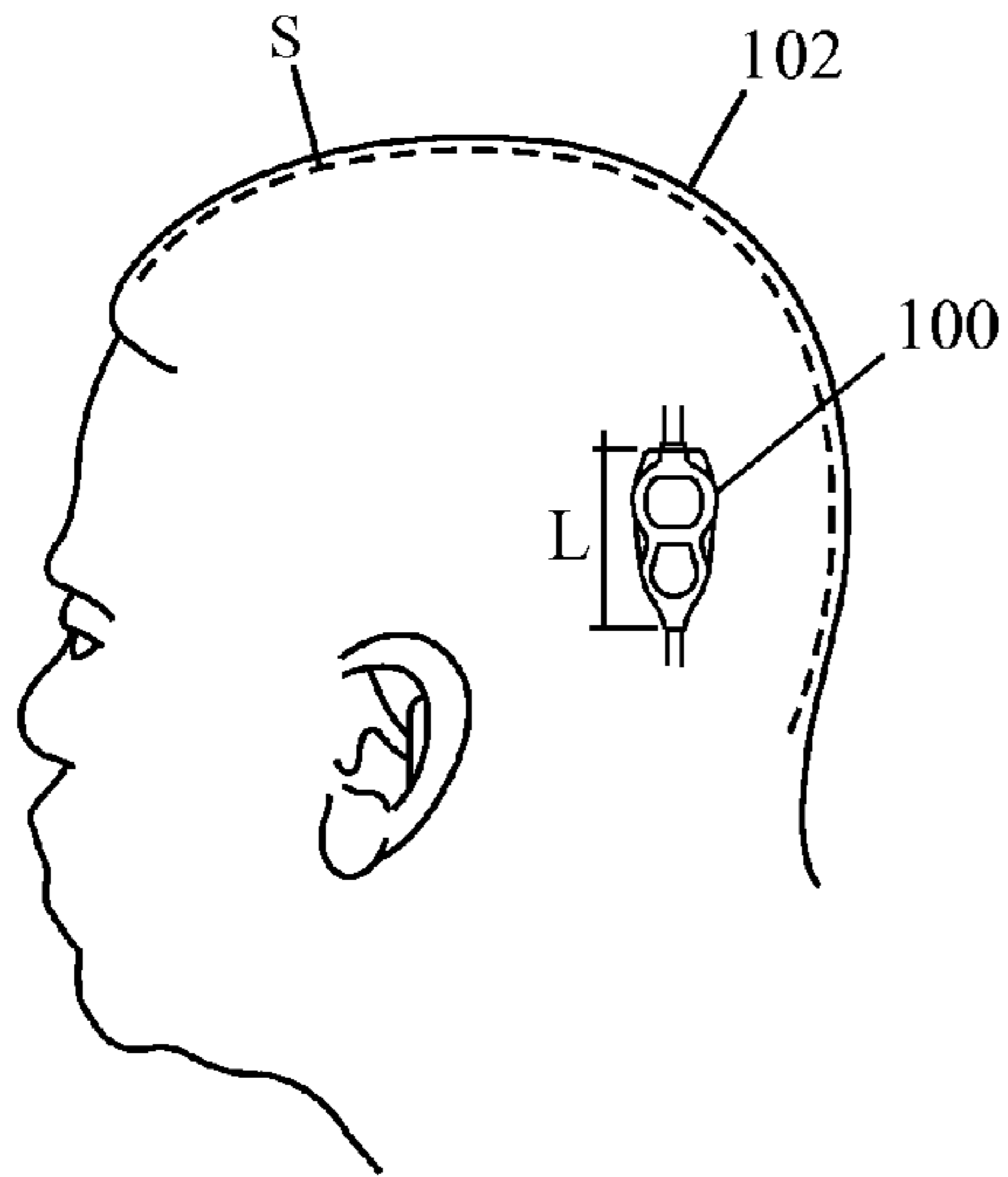


Fig. 2B

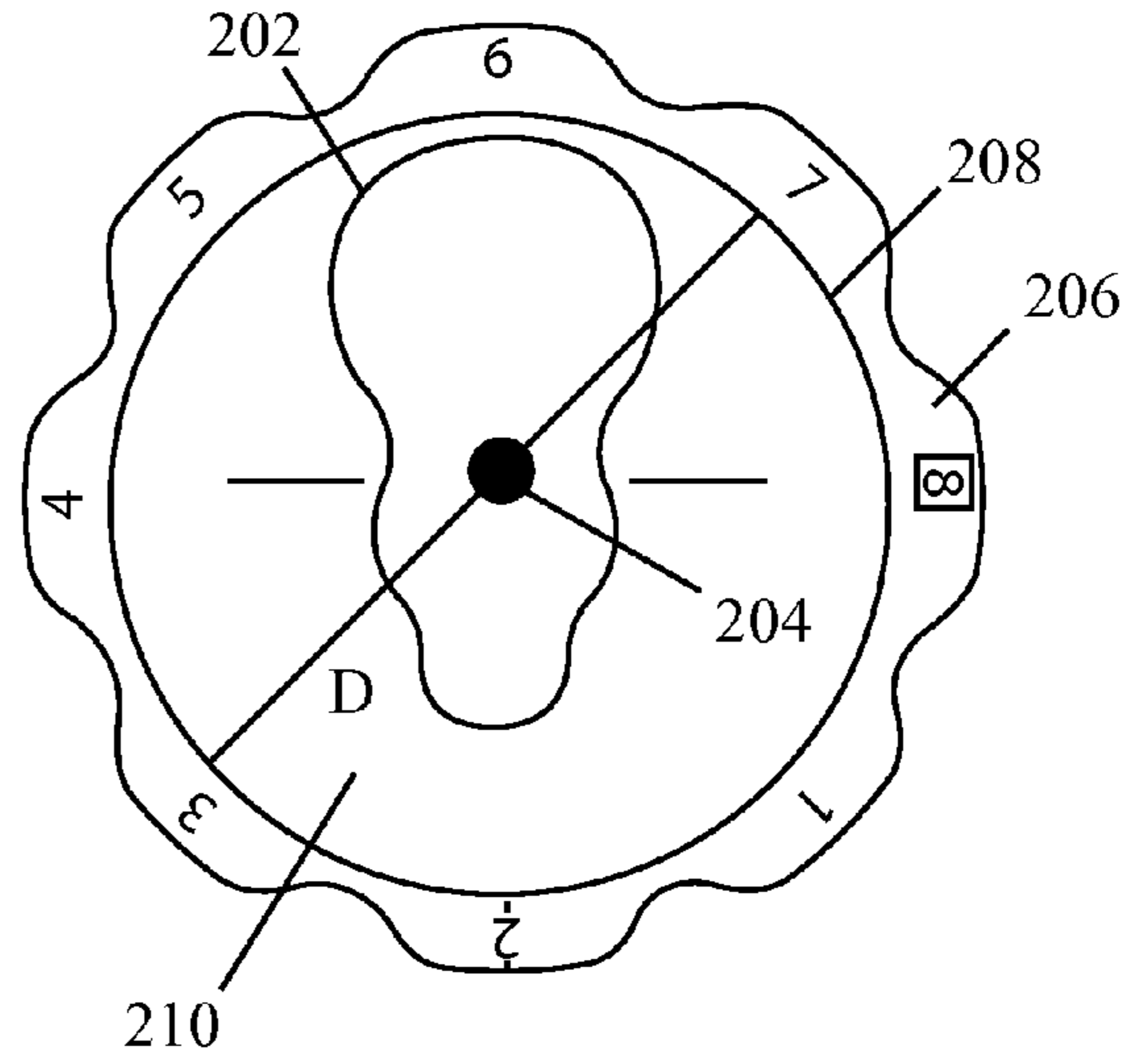


Fig. 2C

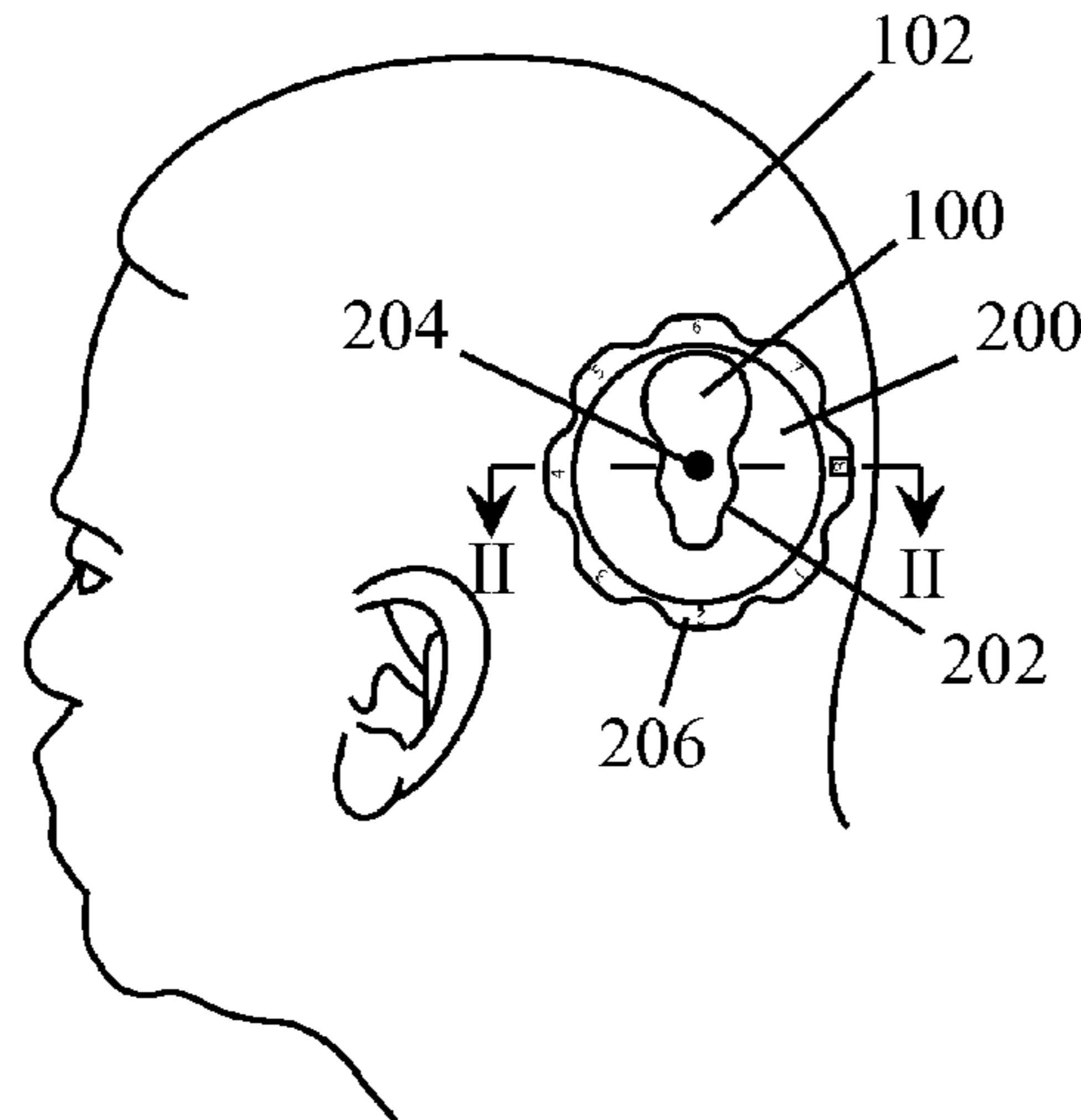


Fig. 2D

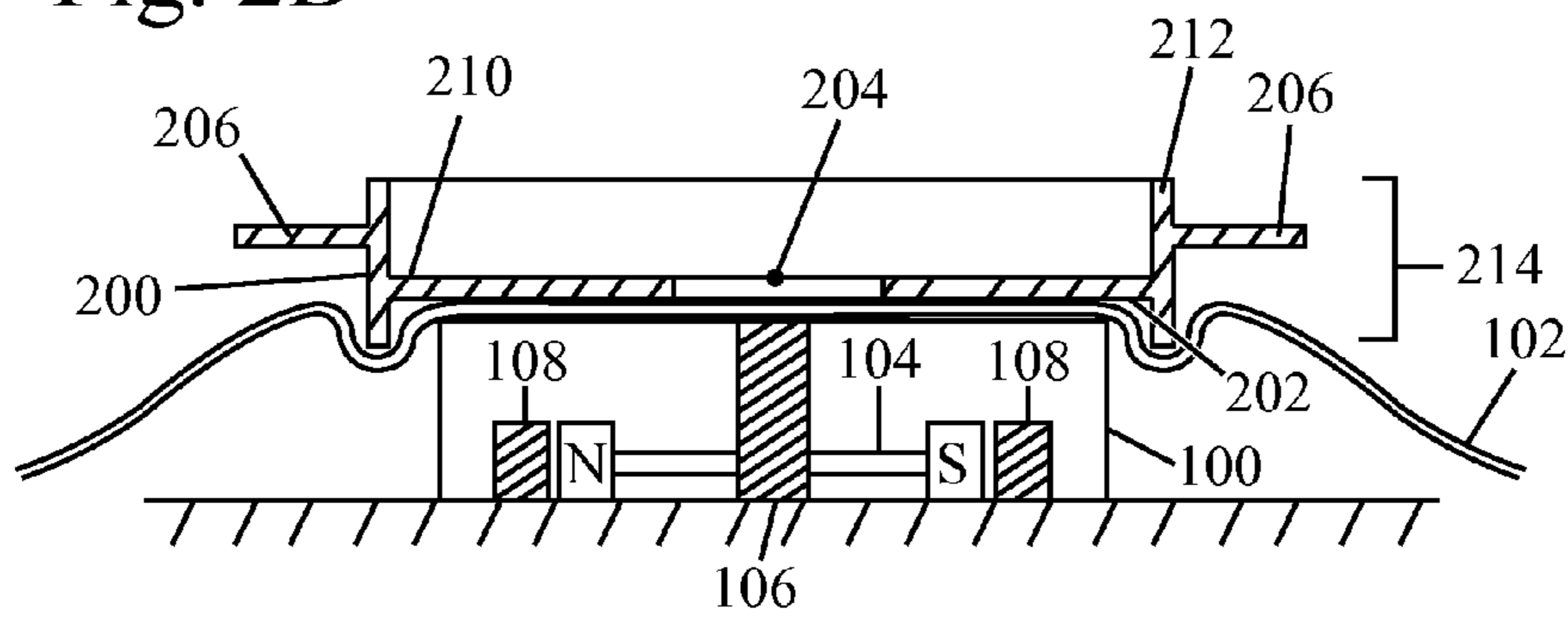


Fig. 3A

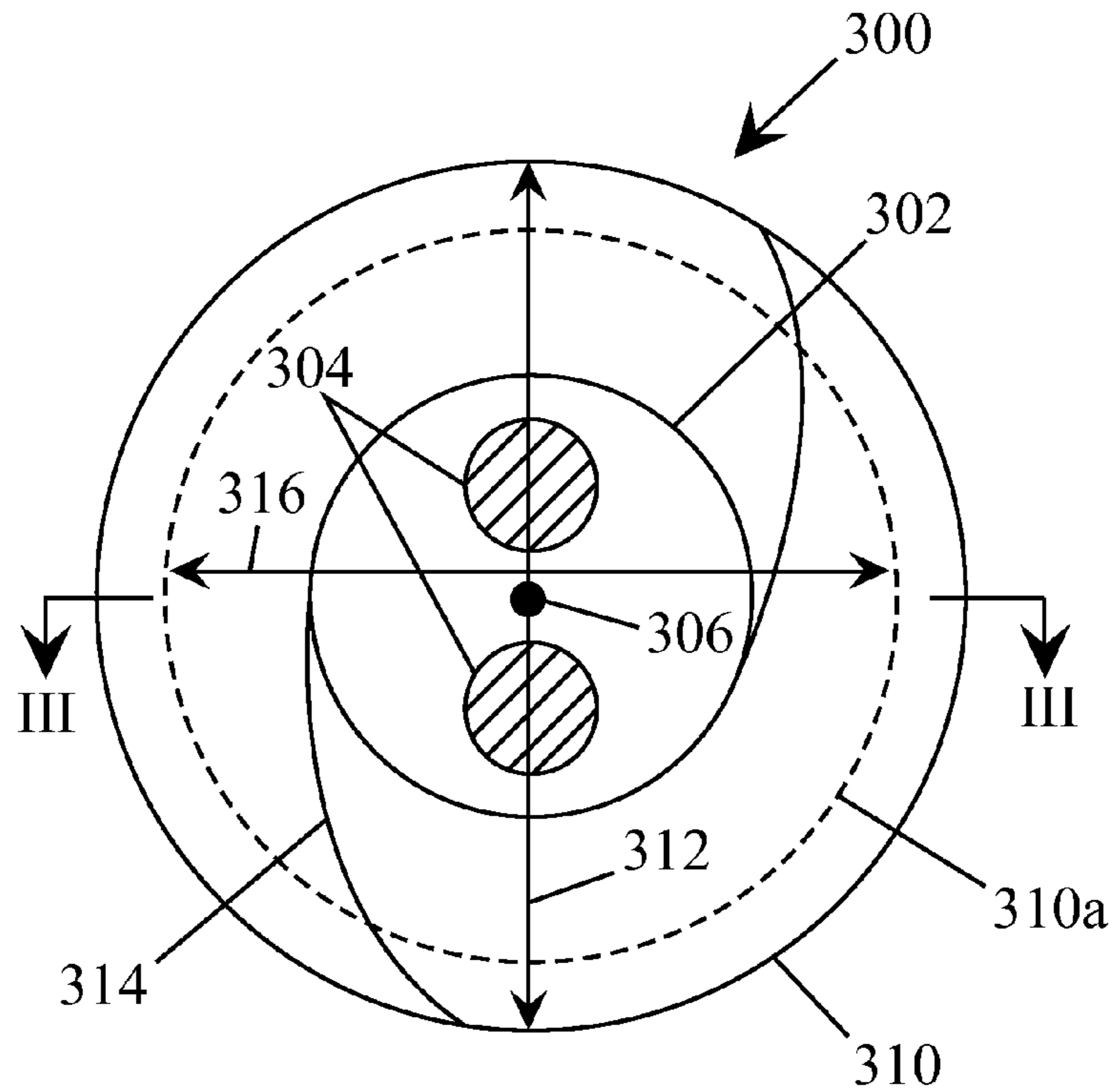


Fig. 3B

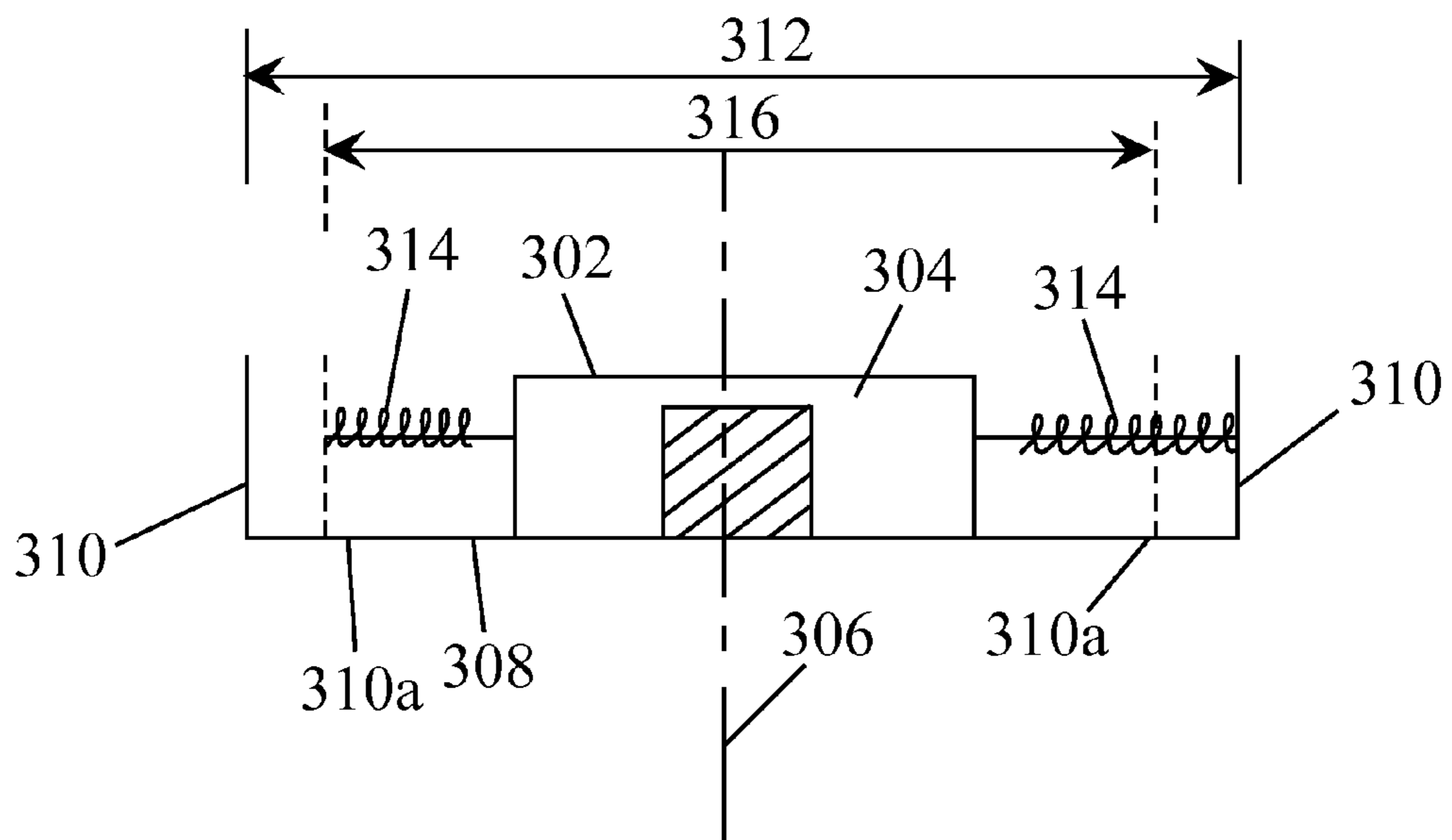


Fig. 3C

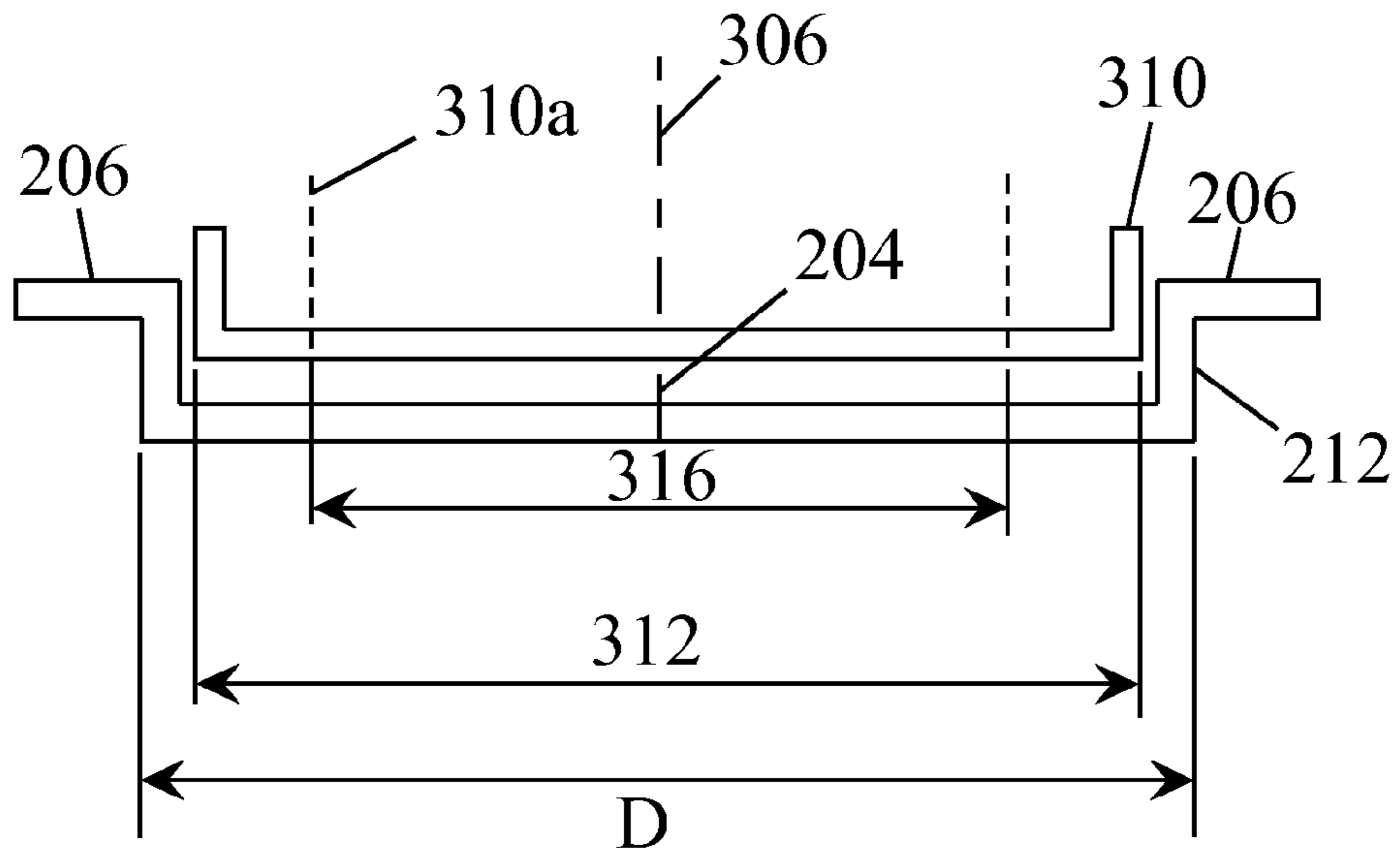


Fig. 3D

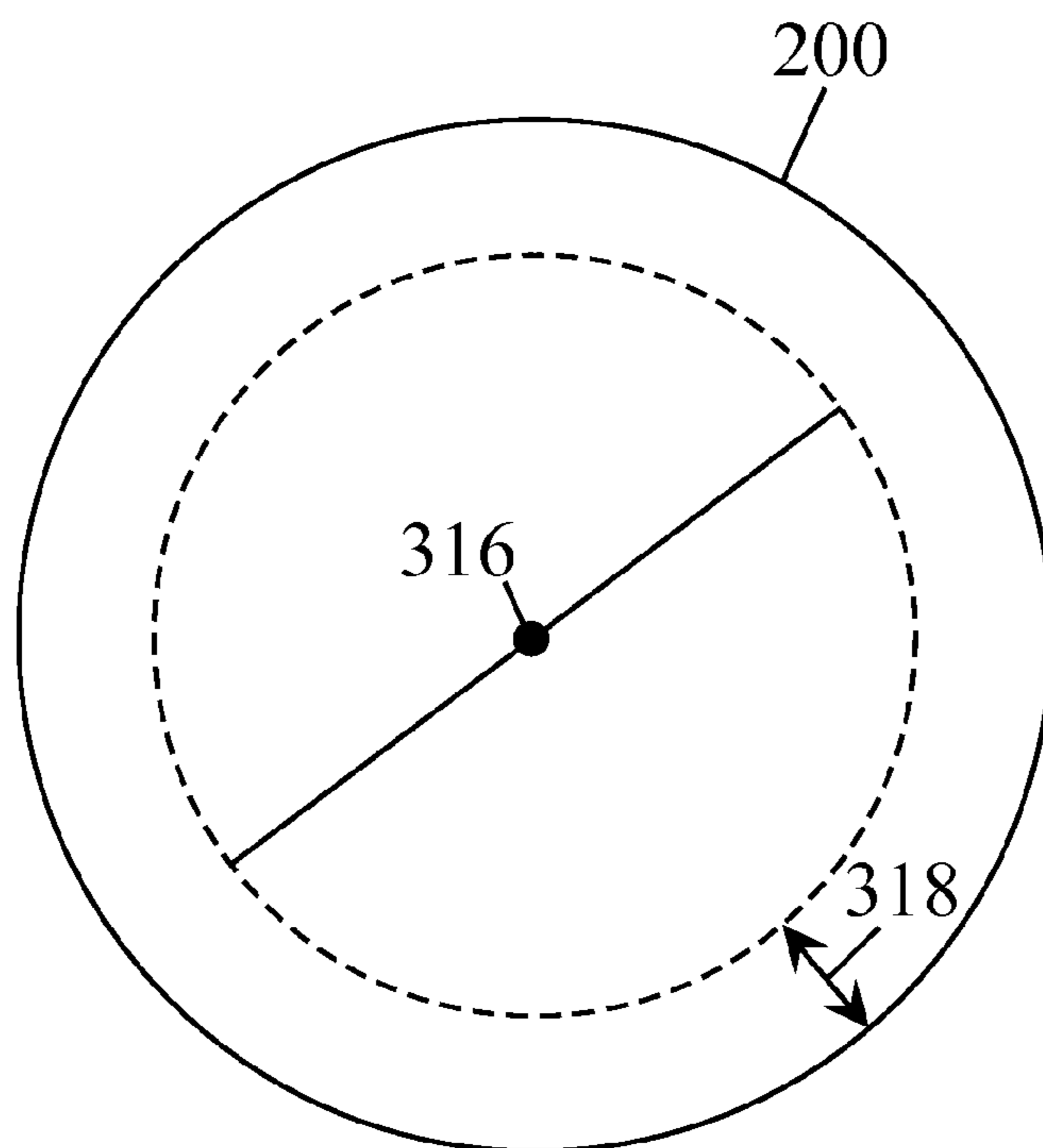


Fig. 4A

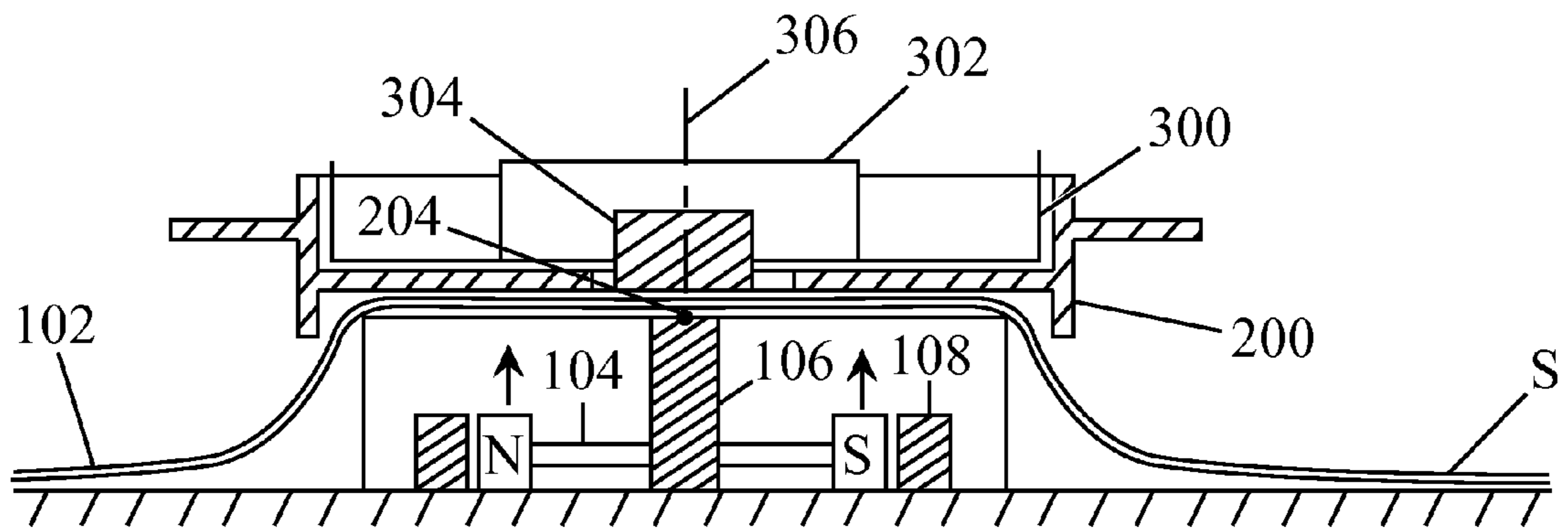


Fig. 4B

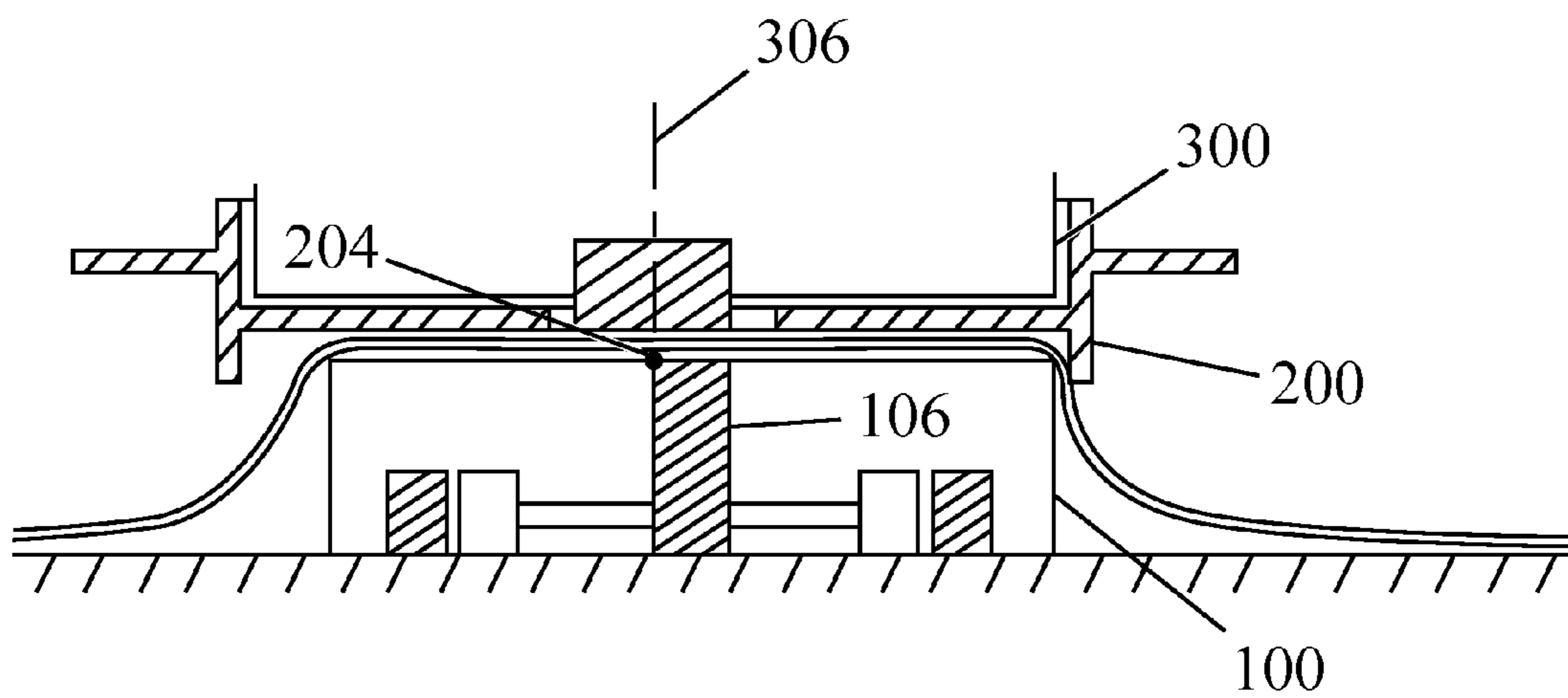


Fig. 5A

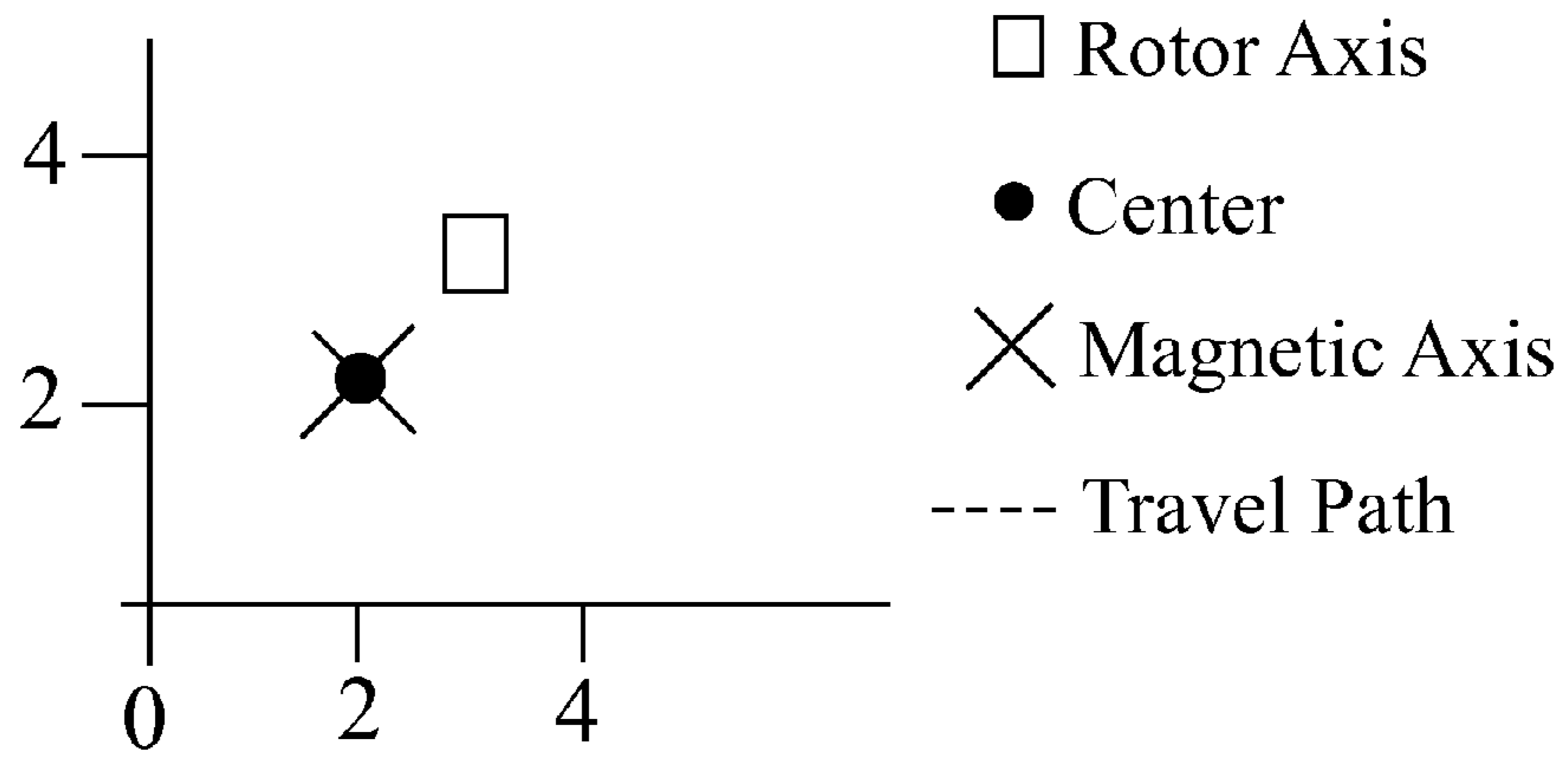


Fig. 5B

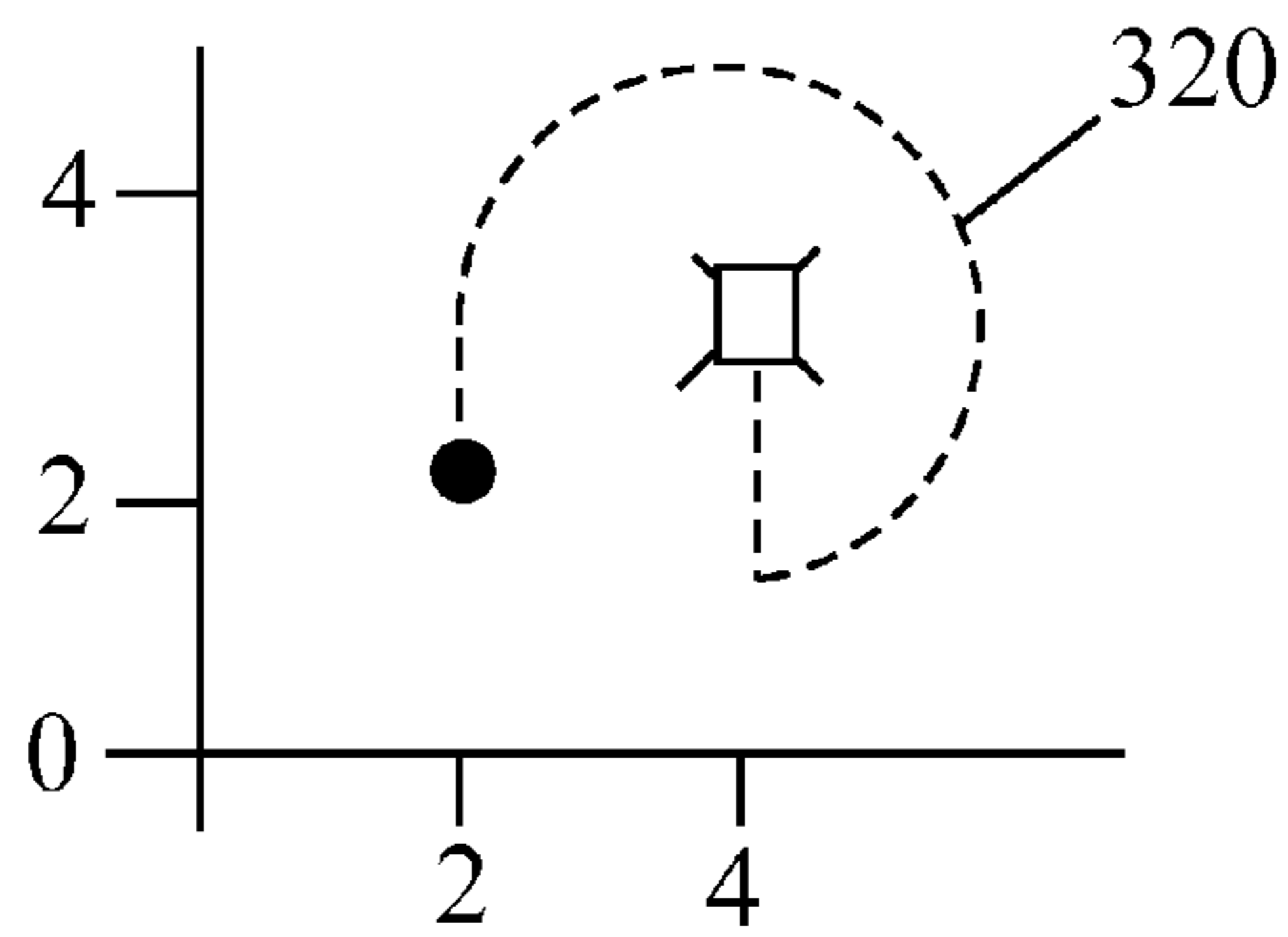


Fig. 5C

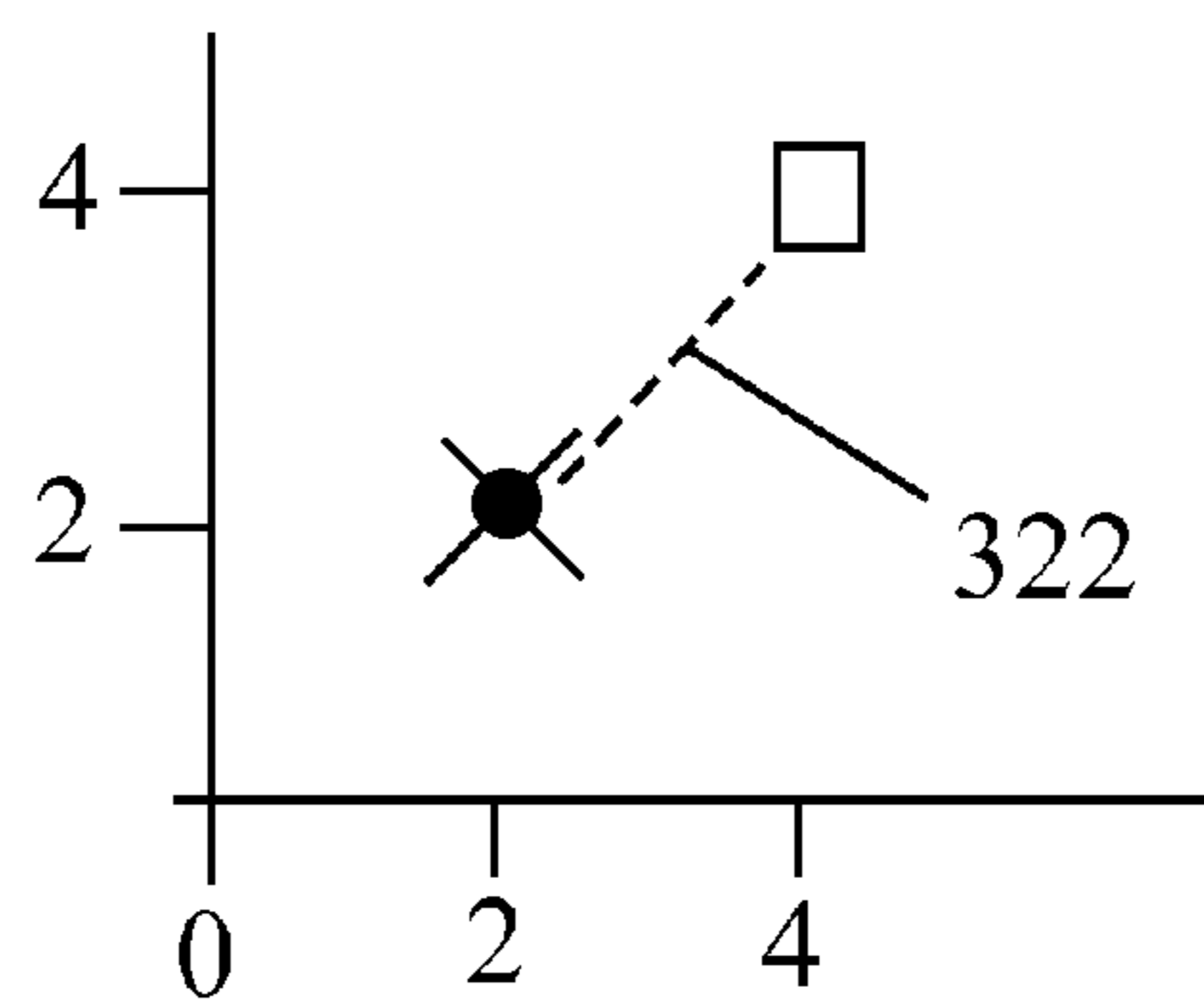


Fig. 6

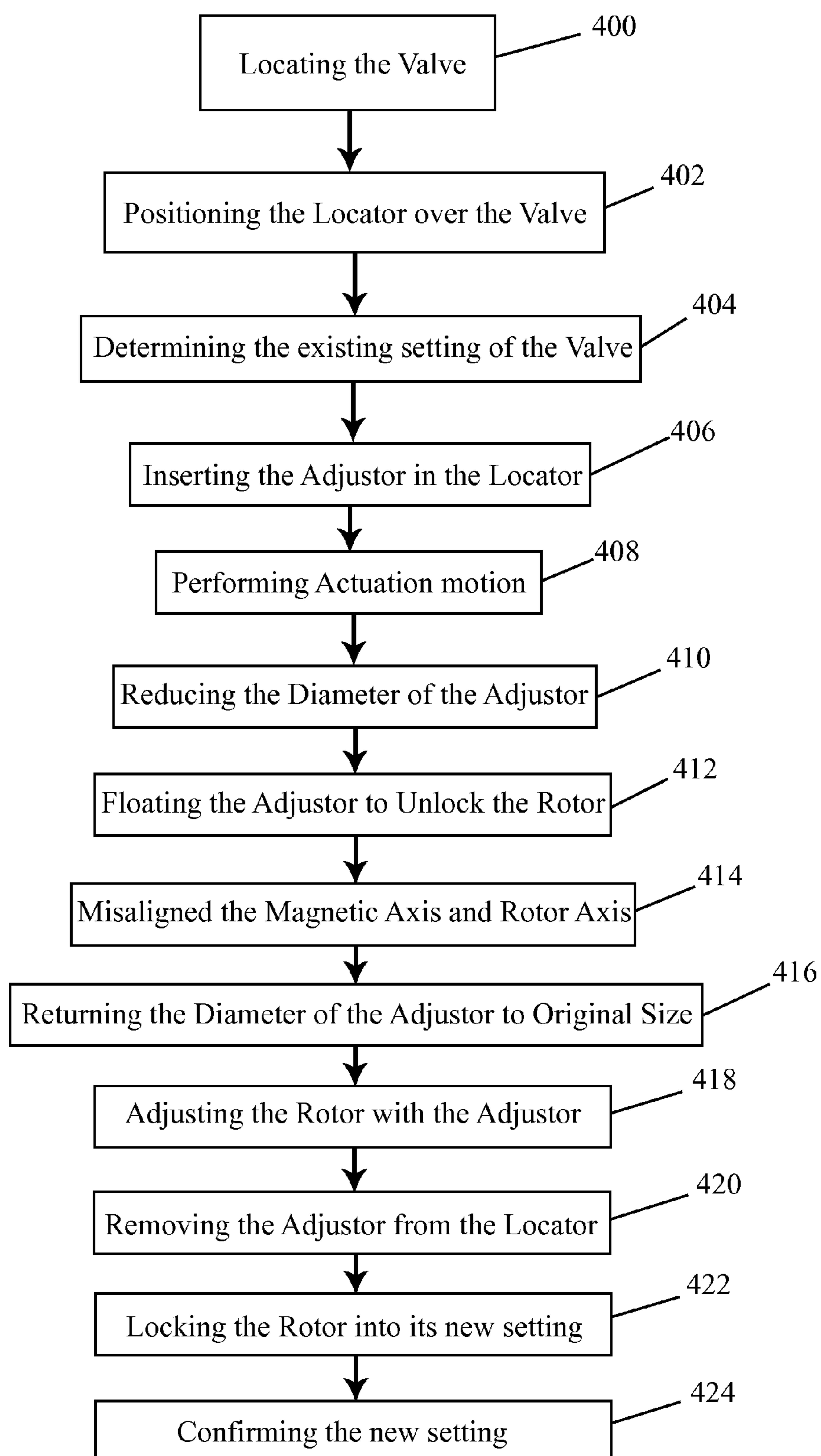


Fig. 7

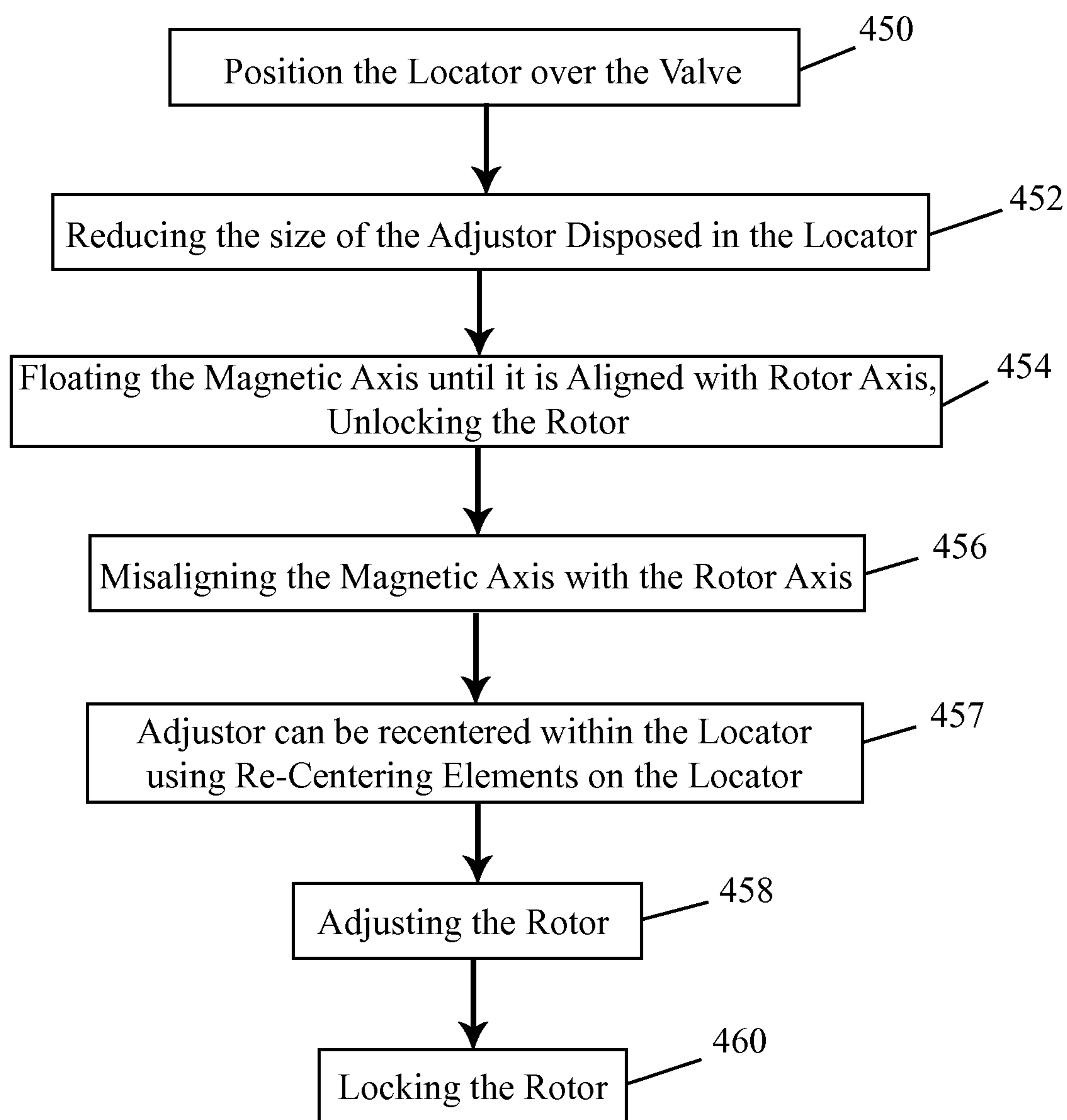


Fig. 8

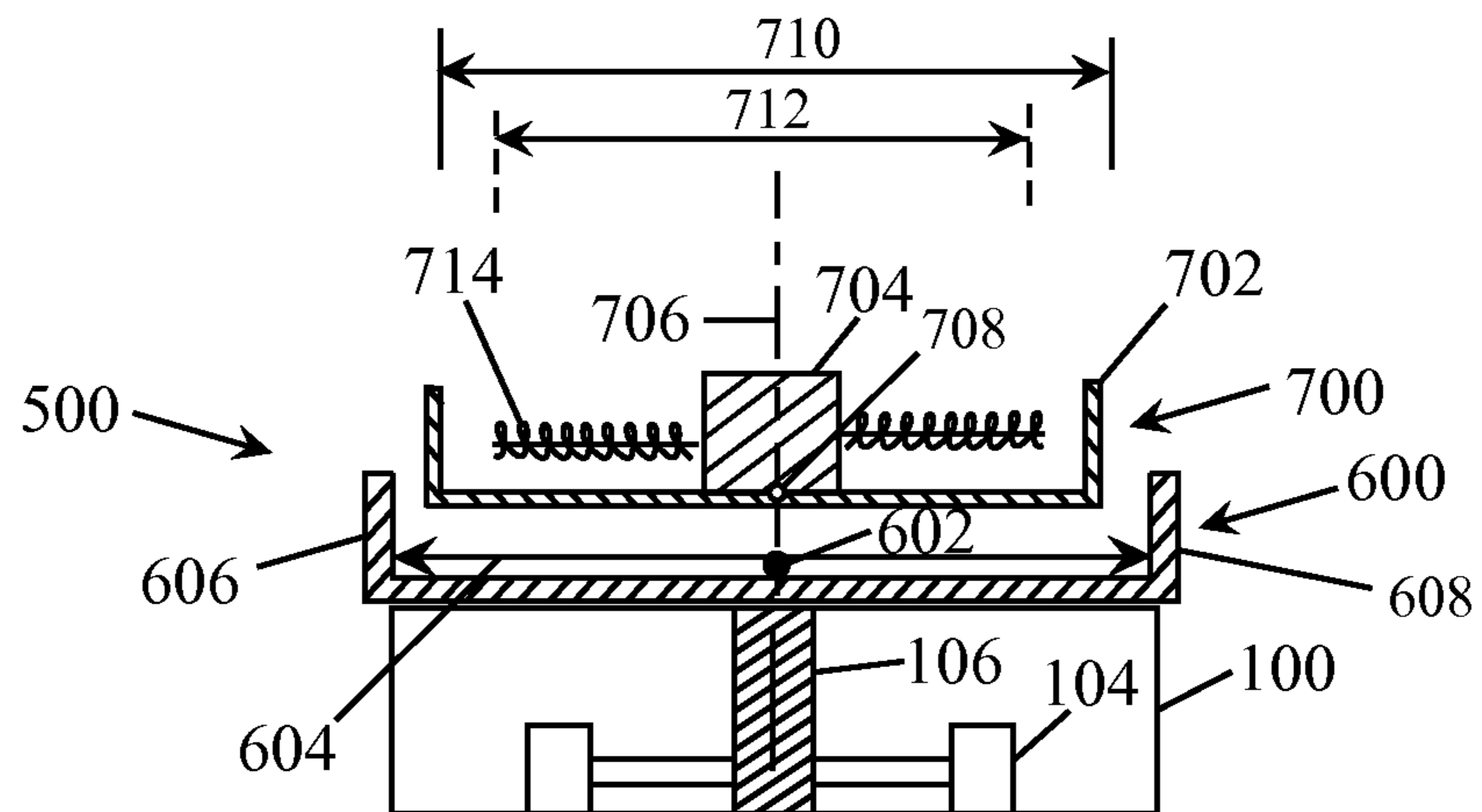
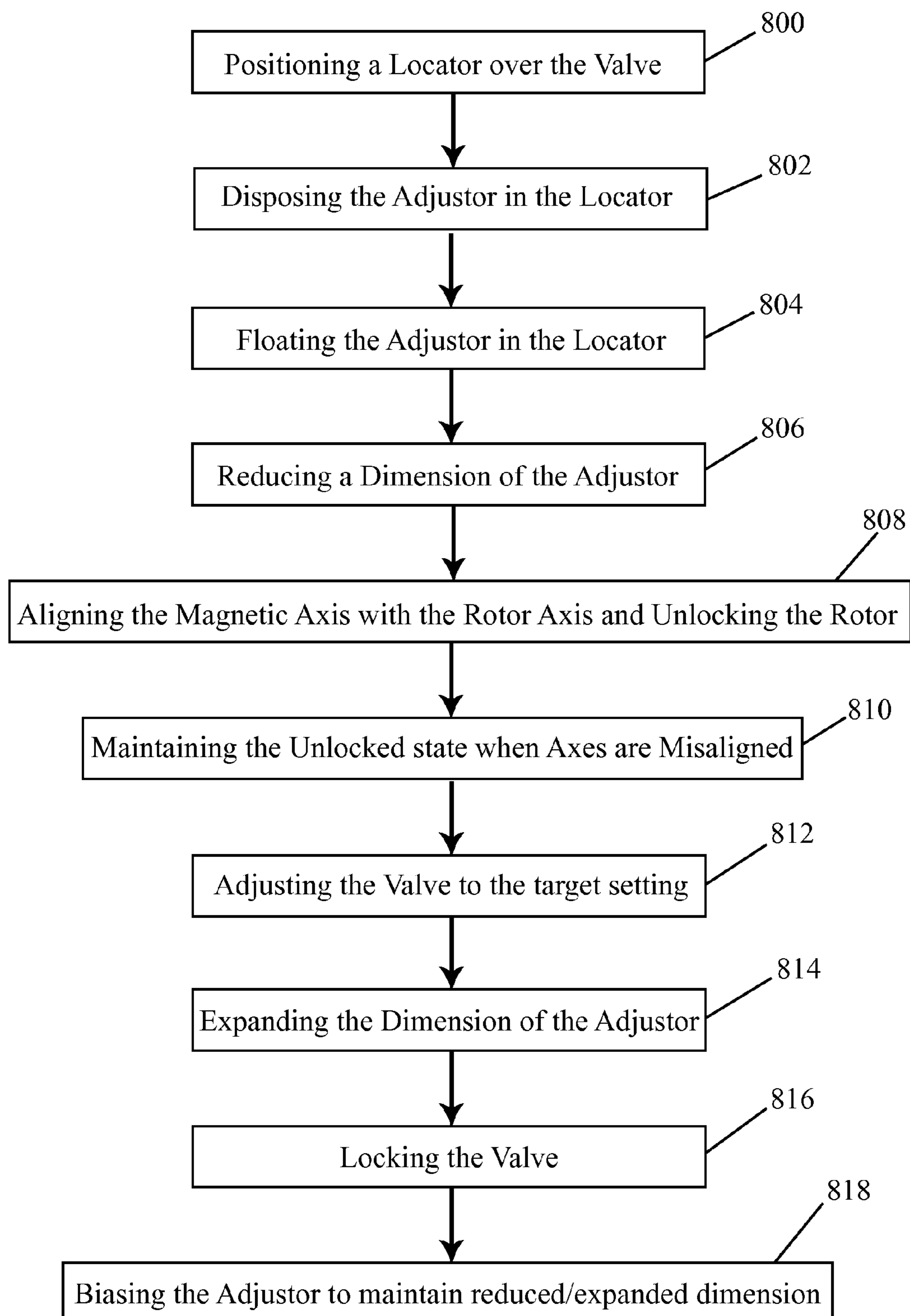
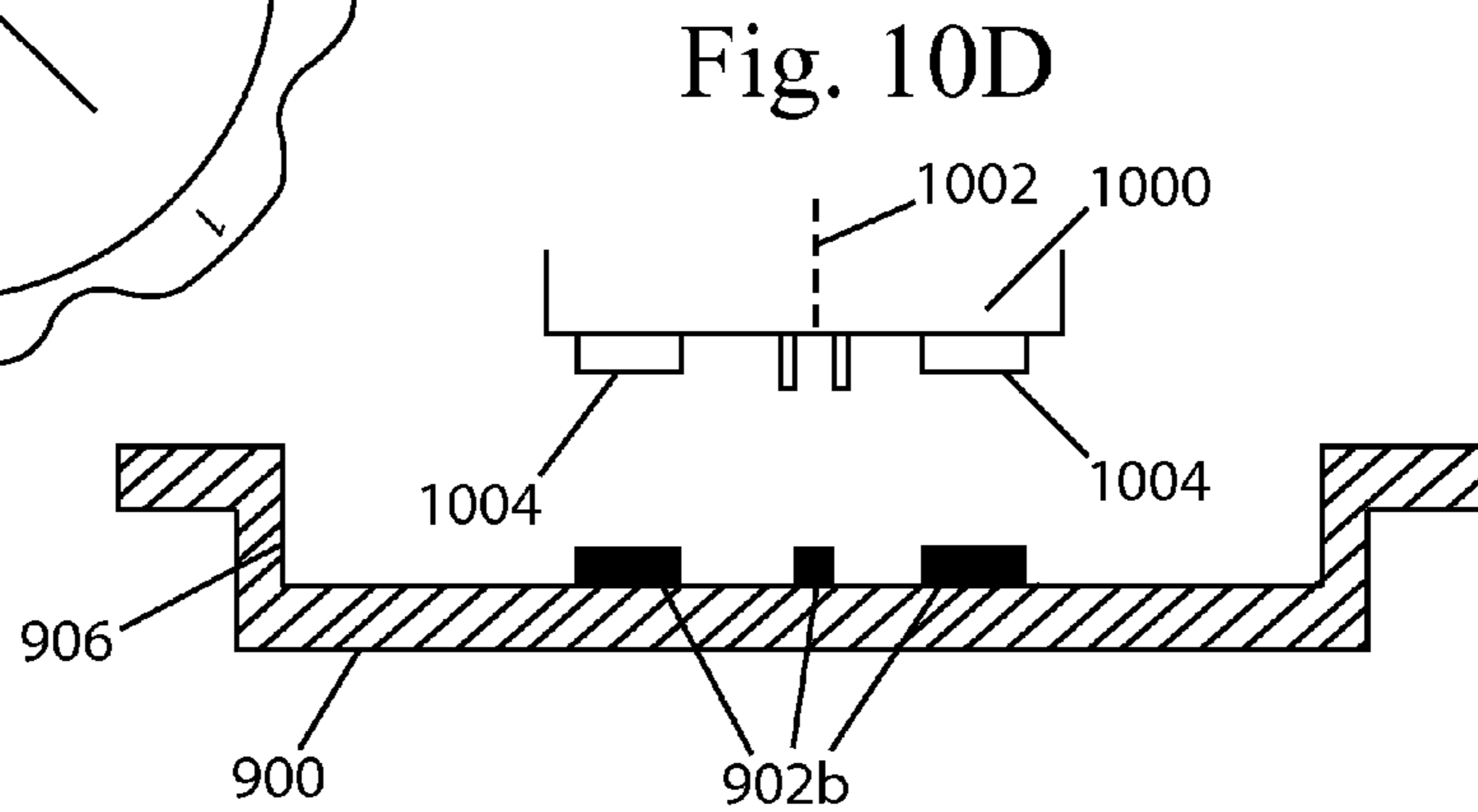
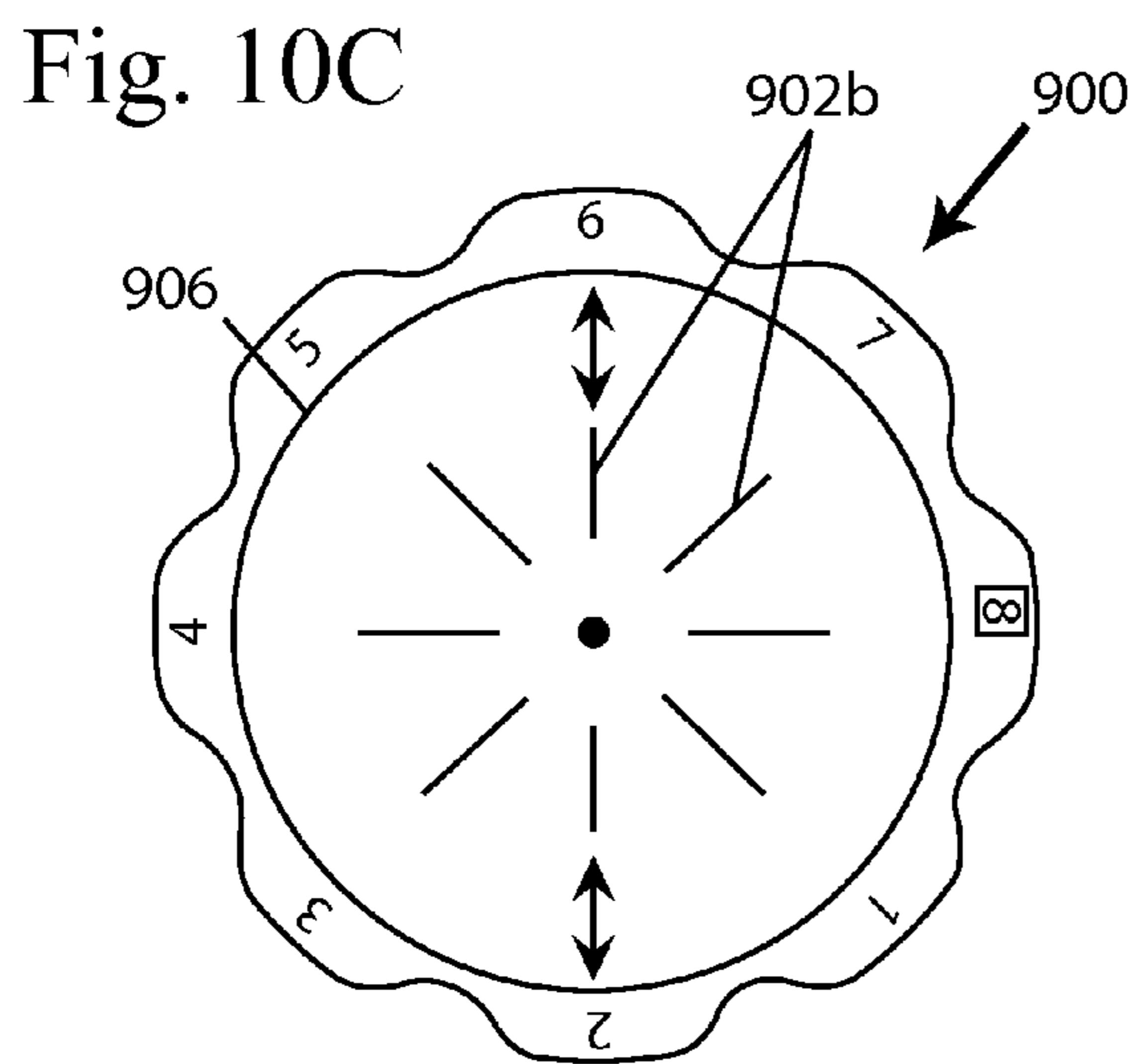
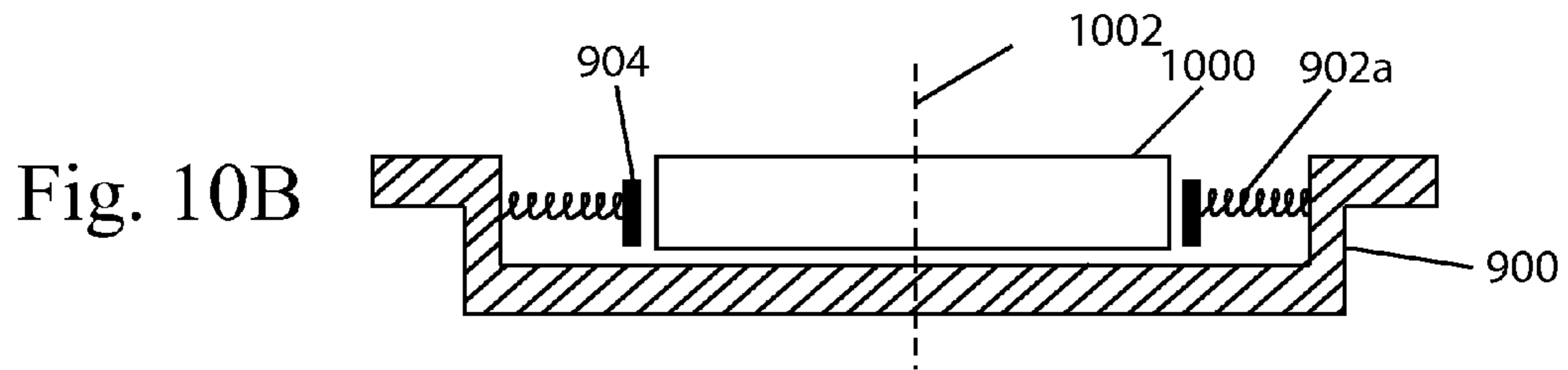
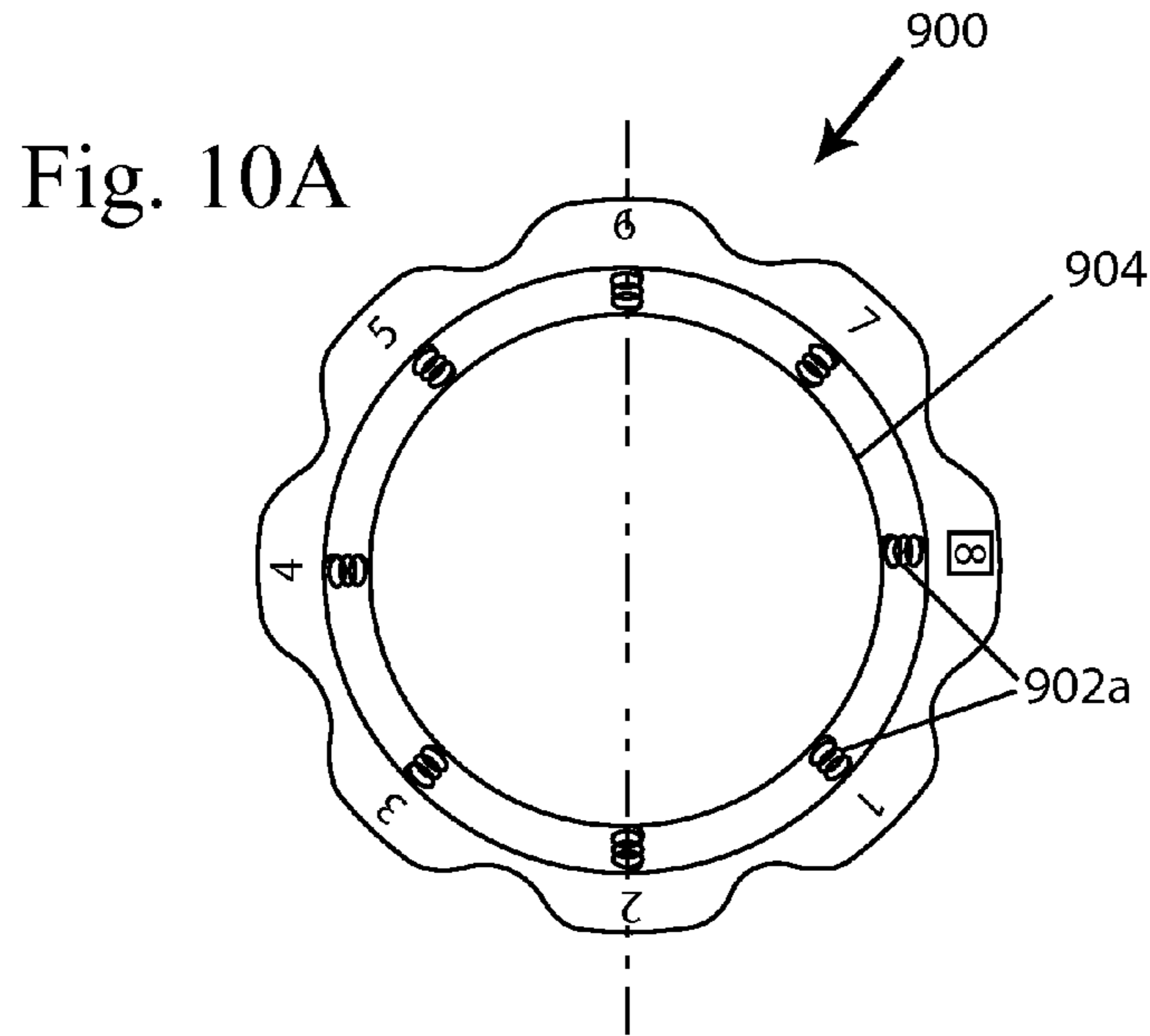


Fig. 9





1

DYNAMIC ADJUSTMENT TOOL FOR PROGRAMMING AN IMPLANTABLE VALVE

FIELD OF THE INVENTION

The invention relates generally to surgically implantable fluid drainage systems. More specifically, the invention relates to extracorporeal tools for setting adjustable valves used for cerebrospinal fluid drainage.

BACKGROUND

Hydrocephalus is a neurological condition caused by the abnormal accumulation of cerebrospinal fluid (CSF) within the ventricles, or cavities, of the brain. Hydrocephalus, which can affect infants, children and adults, arises when the normal drainage of CSF in the brain is blocked in some way. Such blockage can be caused by a number of factors, including, for example, genetic predisposition, intraventricular or intracranial hemorrhage, infections such as meningitis, or head trauma. Blockage of the flow of CSF consequently creates an imbalance between the rate at which CSF is produced by the ventricular system and the rate at which CSF is absorbed into the bloodstream. This imbalance increases pressure on the brain and causes the ventricles to enlarge. Left untreated, hydrocephalus can result in serious medical conditions, including subdural hematoma, compression of the brain tissue, and impaired blood flow.

Hydrocephalus is most often treated by surgically inserting a shunt system to divert the flow of CSF from the ventricle to another area of the body, such as the right atrium, the peritoneum, or other locations in the body where CSF can be absorbed as part of the circulatory system. Various shunt systems have been developed for the treatment of hydrocephalus. Typically, shunt systems include a ventricular catheter, a shunt valve and a drainage catheter. At one end of the shunt system, the ventricular catheter can have a first end that is inserted through a hole in the skull of a patient, such that the first end resides within the ventricle of a patient, and a second end of the ventricular catheter that is typically coupled to the inlet portion of the shunt valve. The first end of the ventricular catheter can contain multiple holes or pores to allow CSF to enter the shunt system. At the other end of the shunt system, the drainage catheter has a first end that is attached to the outlet portion of the shunt valve and a second end that is configured to allow CSF to exit the shunt system for reabsorption into the bloodstream. Typically, the shunt valve is palpable by the physician through the patient's skin after implantation.

Shunt valves, which can have a variety of configurations, can be designed to allow adjustment of their fluid drainage characteristics after implantation. It is generally preferred to enable external adjustment of the pressure threshold to avoid invasive surgical procedures each time an adjustment is required. In some shunt systems, the shunt valve contains a magnetized rotor to control the pressure threshold of the valve. Physicians can then use an external adjustment mechanism, such as a magnetic programmer containing a powerful magnet, to adjust the pressure threshold of the shunt valve. One issue with magnetically programmable valves is a potential for unintentionally adjusting the valve by the misapplication of an external magnetic field. Unintentional adjustment of the valve could lead to either the overdrainage or underdrainage of CSF, which can result in dangerous conditions, such as subdural hematoma. For example, the direction of physical approach to the valve by a magnetic programmer, or an inappropriate initial rotational orientation of a magnetic

2

programmer with respect to the valve, has the potential to inadvertently change a setting of the valve.

It is also important to be able to externally read or verify the setting of the valve. With some adjustable valves, x-ray images are used to determine the current setting of the valve, before and after adjustment. With other adjustable valves, the orientation of the rotor in the valve can be read magnetically, using a magnetic compass-like device positioned above the valve, outside the skin of the patient.

Although tools and methods exist for adjusting CSF shunt valve settings, as do other tools and methods for reading a valve setting, some are difficult to get the magnetic axis of the adjustment tool to align with the magnetic axis of the rotor of the valve. If the axes are not aligned, the rotor cannot be set in the adjusting position. Unfortunately, there is no way for the user to determine if the valve's rotors are in the adjusting position. Thus, the user believes that the valve's rotors are in the adjusting position, makes the adjustment, and then on checking the setting, finds that the adjustment was not made. The user may repeat this process numerous times, each time attempting to align the axes to then find the adjustment was not made.

Thus, a need exists for a magnetically programmable valve systems having reduced probability of unintentional adjustment, as well as a tool and method that allows for ease of aligning the magnetic and rotor axes necessary to allow adjustment of an implantable valve's settings.

SUMMARY

Accordingly, the present invention provides tools and methods for externally changing a setting of a magnetically adjustable, implantable valve. An example of a tool for changing a current setting of a magnetically readable and settable valve implanted in a living being is described below. The valve has an internal rotor rotatable about a rotor axis having a locked and an unlocked state. The tool includes a locator having a center aligned with the rotor axis when the locator is disposed over the valve. In this example, the locator can have a bottom with a cut-out of the valve or can be a ring. The locator can also have a first dimension approximately perpendicular with the rotor axis. The first dimension can be a diameter of the locator. A wall of the locator can have a second dimension approximately perpendicular to the first dimension. The wall can form a volume in that the locator has a depth to allow an adjustor to be disposed therein.

The adjustor has an adjustable outer wall that fits at least partially within the wall of the ring. The adjustor has at least one magnet having a magnetic axis. The magnet has a strong enough magnetic field to unlock the internal rotor of the valve. In one example, the magnet is disposed approximately in a center of the adjustable outer wall. The adjustable outer wall has a first position dimension approximately equal to or less than the first dimension of the locator. This sizing permits the adjustor to rotate about the center of the locator. In an example, the only movement of the adjustor permitted within the locator is rotational about the center, accounting for a small amount of play typical between separately formed parts.

The magnetic axis can align with the center of the locator when the adjustor is disposed within and the adjustable outer wall has the first position dimension. The adjustable outer wall also has a second position dimension less than the first dimension and less than the first position dimension. This sizing permits the adjustor to move more freely inside the locator. The adjustor can move at least lateral, rotational, and orbital in the locator. This movement can misalign the mag-

netic axis with the center of the locator when the adjustor is disposed within and the adjustable outer wall has the second position dimension. When the magnetic axis aligns with the rotor axis, the rotor moves into the unlocked state and the rotation of the adjustor can set the valve when unlocked. The rotor can return to the locked state once the adjustor is removed from the locator. Once the magnet unlocks the rotor, the magnet maintains the rotor in the unlocked state even when the magnetic axis and rotor axis are misaligned.

A plurality of indicators can be disposed on the wall indicating one or more valve settings. In one example, the indicators can be notches or lines on the locator or tabs extending from the wall.

A flexible element can bias the adjustable outer wall to one of the first position dimension or the second position dimension. Thus, the adjustor can be in either position in its static state. The flexible element can be compressed or expanded to allow the adjustable outer wall to move between position dimensions and then move back to its static state. The flexible element can be locked in place or held under force by the user to achieve the non-static position.

All of the above dimension can be diameters.

A method for adjusting the magnetically adjustable valve from a current setting to a target setting is described below. The method can include positioning a locator over the valve and disposing the adjustor at least partially within the locator. Then, permitting the adjustor to move at least two of lateral, rotational, and orbital within the locator. This can include the step of reducing a dimension of the adjustor to less than a comparable dimension of the locator. In other words, reducing the diameter of the adjustor in comparison to the diameter of the locator, the above movement allows the adjustor to be non-concentric with the locator. During the movement of the adjustor, aligning the magnetic axis with the rotor axis displaces the rotor into the unlocked state. When the magnetic axis and the rotor axis are misaligned, the magnet still maintains the unlocked state. The misalignment of the magnetic axis and the rotor axis can occur due to a misalignment of the locator over the valve. This misalignment occurs when the user cannot place the locator in the precise position to align the two axes. Then, the user can adjust the valve to the target setting. Adjusting the valve can include expanding the dimension of the adjustor to permit the adjustor to rotate within the locator. The valve can then be locked again by placing the valve rotor in the locked state by removing the adjustor from the locator. Further, the adjustor can be biased to maintain one of the reduced dimension or the expanded dimension.

BRIEF DESCRIPTION OF THE DRAWINGS

This invention is described with particularity in the appended claims. The above and further aspects of this invention may be better understood by referring to the following description in conjunction with the accompanying drawings, in which like numerals indicate like structural elements and features in various figures. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

The drawing figures depict one or more implementations in accord with the present teachings, by way of example only, not by way of limitation. In the figures, like reference numerals refer to the same or similar elements.

FIG. 1A is a cross-section along line I-I of FIG. 1B illustrating an example of the valve in the locked rotor position;

FIG. 1B is a top view of the valve;

FIG. 1C is a cross-section view along line I-I of FIG. 1B illustrating the valve in the unlocked rotor position;

FIG. 2A is an illustration of the valve implanted in a patient;

FIG. 2B is a top view of an example of a locator;

FIG. 2C is an illustration of the valve and locator as used on a patient;

FIG. 2D is a cross-sectional view along line II-II of FIG. 2C illustrating the valve and locator in use;

FIG. 3A is a top cross-sectional view of an example of an adjustor;

FIG. 3B is a cross-sectional view along line III-III of FIG. 3A illustrating the adjustor;

FIG. 3C is a cross-section of an example the adjustor inside the locator;

FIG. 3D is a top view of an example of the adjustor in the second wall diameter position inside the adjustor;

FIG. 4A is a cross-section of the valve, locator and adjustor in alignment;

FIG. 4B is a cross-section of the valve, locator and adjustor out of alignment;

FIGS. 5A-5C are graphs illustrating the position of the rotor axis, center and magnetic axis over time;

FIG. 6 is flow chart illustrating an example of a method of adjusting an implanted valve;

FIG. 7 is flow chart illustrating another example of a method of adjusting an implanted valve;

FIG. 8 is a further example of an implanted valve adjustment tool;

FIG. 9 is flow chart illustrating a further example of a method of adjusting an implanted valve;

FIGS. 10A and 10C are top views of a locator with various re-centering elements; and

FIGS. 10B and 10D are cross-section views of FIGS. 10A and 10C, respectively.

DETAILED DESCRIPTION

In the following detailed description, numerous specific details are set forth by way of examples in order to provide a thorough understanding of the relevant teachings. However, it should be apparent to those skilled in the art that the present teachings may be practiced without such details. In other instances, well known methods, procedures, components, and/or circuitry have been described at a relatively high-level, without detail, in order to avoid unnecessarily obscuring aspects of the present teachings.

Methods and integrated tools of the present invention enable a physician to consistently and reliably change a setting of (adjust) an implantable, magnetically settable valve (valve) from a current setting to a target setting using a dynamic adjustment tool. In an example, the valve is used to control, via its setting, at least one of CSF drainage flow and pressure for a patient with hydrocephalus, is implanted under a patient's scalp or another portion of the patient's skin, and is adjustable from outside (above) the patient's skin.

Other tools and methods for extracorporeally reading and adjusting a hydrocephalus valve are disclosed in U.S. Pat. No. 8,038,641 entitled "Tools and Methods for Programming an Implantable Valve", which is hereby incorporated by reference in its entirety. Within the scope of the present invention, features of the various examples disclosed herein can be used in any combination to construct additional integrated tools and methods for reading and adjusting an implantable valve.

Hydrocephalus valves read and adjusted by tools and methods of the present invention include a magnetic rotor, the rotational orientation of which about a rotor axis is indicative of, and used to modify, the current setting of the valve. An externally applied magnetic field can be used to rotate the

5

rotor about the rotor axis to adjust the valve to the target setting. Additionally, some hydrocephalus valves include a locking element to prevent accidental adjusting of the valve by stray magnetic fields, requiring that a magnetic field for adjusting the valve be applied along the rotor axis to unlock the valve before turning the rotor about the rotor axis.

Any noninvasive means for applying a magnetic field for adjusting the valve, or for sensing the orientation of the rotor to read the valve, can be incorporated in tools and methods of the present invention. In some embodiments, the externally applied magnetic field for adjusting the valve is provided using one or more permanent magnet that can be physically oriented about the rotor axis. In other embodiments, the externally applied magnetic field for adjusting the valve is provided using one or more electromagnet having a magnetic field that can be electronically or physically oriented about the rotor axis.

Reading the current valve setting is accomplished by sensing the rotational orientation of the magnetic rotor about the rotor axis. In some embodiments, sensing the rotational orientation is accomplished using a magnetically responsive mechanical device such as a magnetic compass. In other embodiments, sensing the rotational orientation is accomplished using one or more electronic sensors capable of measuring a magnetic field.

FIGS. 1A, 1B, and 1C illustrate a generalized implantable valve 100 implanted beneath a patient's skin 102. The valve 100 includes a magnetic rotor 104 having a rotor axis 106 about which the rotor 104 can be rotated by application of a magnetic field, to adjust the valve 100. In an example, the valve 100 has a plurality of predetermined settings corresponding to a plurality of predetermined rotational orientations of the rotor 104 about the rotor axis 106. In an example, the plurality of settings comprises eight settings.

It is to be understood that the valve 100 can be any magnetically settable, implantable valve comprising a magnetically rotatable rotor, and further including valves that can be magnetically unlocked. In an embodiment, the valve 100 is unlocked for rotation about the rotor axis 106 by a displacement of the rotor 104 along the rotor axis 106, the displacement provided by application an attractive magnetic field along the rotor axis 106. In a further embodiment, the attractive magnetic field and the magnetic field for rotating the rotor about the rotor axis are provided by a single magnetic source that can be either a permanent magnet or an electromagnet.

FIG. 1A is a cross-section of the valve 100 when the rotor 104 is in the locked position. The rotor 104 is set in a locking element 108. The locking element 108 is configured to prevent the rotor 104 from rotating around the rotor axis 106 to an alternative setting. Note, that in some examples, the rotor 104 can rotate within the valve 100 while locked. FIG. 1B illustrates that the locking element 108 is spaced around the rotor axis 106 to allow for the predetermined rotational orientations of the rotor 104 about the rotor axis 106. The predetermined rotational orientations of the rotor 104 correspond to flow and pressure settings of the valve 100. For example, the valve 100 can be set to flow rates between 5-50 ml/hr to maintain pressures between 0-500 mm H₂O, between eight distinct settings. FIG. 1C is the same cross-section as FIG. 1A, except for the fact that the rotor 104 has been displaced along the rotor axis 106. This displacement removes the rotor 104 from the locking element 108 and the rotor 104 is now free to rotate around the rotor axis 106. Once rotated about the rotor axis 106 to a new position, the rotor 104 can be set back within the locking element 108 to lock the rotor 104 such that it is confined in the new position.

6

FIG. 2A illustrates the valve 100 implanted under the skin 102 of a patient's skull S. Once implanted, the valve is under the skin and typically covered by hair. Additionally, the area surrounding the valve may experience localized swelling, especially after surgery. To locate the valve 100 under the skin 102, the user typically palpates the skin 102 until she can feel the valve 100. In one example, to facilitate the adjustment of the valve, a locator 200 is placed over the valve 100 on top of the skin 102 of the skull S.

FIG. 2B illustrates an example of the locator 200. The locator 200 can be typically circular and can have a diameter D larger than a length L of the valve 100. The locator 200 can have a cut-out 202 or gap shaped similar to the valve 100. This allows the locator 200 to be oriented in the proper direction when placed over the valve 100. The cut-out 202 can be oriented such that once placed over the valve 100 the rotor axis 106 is aligned with a center 204 of the locator 200. While an example can be circular, the locator 200 can have any shape to allow the rotation and translation movements described below. Thus, in one example, the locator 200 can be non-circular and composed of numerous line segments.

The locator 200 can also have indicators 206, these can be petals or tabs extending outside a circumference 208 defined by the diameter D (wherein circumference 208 equals 2×diameter D). FIG. 2C illustrates a top view of the locator 200 placed over the valve 100 on the patient's skull S.

FIG. 2D is a cross section illustrating both the valve 100 and the locator 200. The cut-out 202 of the locator 200 can be placed over the valve 100 and can even receive a small portion of the valve 100, as the skin 102 may allow. The cut-out 202 can be formed in a bottom 210 of the locator 200. The locator 200 also can have a circumferential wall 212 depending from the bottom 210 and, in one example, encircling the entire bottom 210. The indicators 206 can depend from the circumferential wall 212 and a height 214 of the circumferential wall 212 can form a space or volume, within the locator 200.

Turning now to FIGS. 3A and 3B, an example of an adjustor 300 is illustrated. The adjustor 300 is sectioned to see within, and can have a magnetic core 302 including one or more magnets 304 fixed inside the core 302. As above, the magnets 304 can be permanent or electromagnets. In one example, the core 302 can be centered inside the adjustor 300. The magnets 304 can form a magnetic axis 306 which can also be centered inside the core 302 and the adjustor 300. The magnetic axis 306 can be the intersection point of the magnetic fields of the magnets 304, where the magnetic force of the adjustor 300 coupling to the magnetic rotor 104 is the strongest. The adjustor 300 can also have a bottom 308 and a wall 310 extending from the bottom 308 to form a cavity for the core 302. The wall 310 can be a circular perimeter of the adjustor 300 or can be formed from two or more segments. The wall 310 can be held in place at a first wall diameter 312 by one or more resilient elements, (e.g. springs) 314. Upon an actuation motion, which in some examples can be a rotational, twisting, or compressive motion, the springs 314 are compressed or flexed and the wall 310 is drawn toward the core to a second wall position 310a. The second wall position 310a provides a second wall diameter 316. The second wall diameter 316 can be smaller than the first wall diameter 312. Once the actuation motion is released, the springs 314 can be released and the wall can return to the position of the first wall diameter 312. Note, that in one example, the core 302 does not change its position within the adjustor, only the wall 310 changes its relative position.

The resilient elements 314, as described above, can be used to re-center the adjustor 300 within the locator 200. Re-centering, in one example, results in the magnetic axis 306

and the center **204** of the locator **200** being coaxial. However, other elements (not illustrated) within the locator **200** and adjustor **300** that assist in providing some tactile feedback when rotating the adjustor **300** within the locator **200** can also be used to re-center the adjustor **300**, for example, detent balls and cam mechanisms.

As illustrated in FIG. 3C, the first wall diameter **312** is approximately equal to the diameter **D** of the locator **200**, and in one example, smaller. In this way, the adjustor **300** can fit within and rotate inside a portion of the locator **200**. In one example, the bottom of the adjustor **308** can be in contact with the bottom of the locator **210**. When the adjustor **300** is at the first wall diameter **312** position, there can be little or no gap between the adjustor wall **310** and the circumferential wall **212** of the locator **200**. This fit between the two walls **212**, **310** can prevent most or all lateral or orbital movement of the adjustor **300** within the locator **200**. In an example, the only movement permitted when the wall **310** is at the first wall diameter **312** is rotational movement within the locator **200** about the center **204**. This example allows the adjustor **300** to rotate between indicators **206**. In the first wall diameter **312** position, the magnetic axis **306** can be aligned, or coaxial, with the center **204** of the locator **200**.

Once an actuation motion is applied to the adjustor **300** and the wall is in the second wall position **310a**, the second wall diameter **316** is also less than the diameter **D** of the locator **200**.

In an example:

the first wall diameter $312 \leq D$ and the second wall diameter $316 \ll D$.

Alternately:

the second wall diameter $316 < \text{first wall diameter } 312 \leq D$. This reduction in diameter to the second wall diameter **316** allows a gap **318** between the adjustor wall **310a** and the circumferential wall **212** of the locator **200**. This gap **318** allows for lateral and orbital movement of the adjustor **300** within the locator **200**. This movement can allow the magnetic axis **306** to come out of alignment, or be non-coaxial, with the center **204** of the locator **200**. The adjustor **300** can be moved laterally, up down, left, and right in relation the position of the locator **200** in FIG. 3D, or can be orbited inside the locator **200** by placing the walls **212**, **310a** in contact with each other and moving the adjustor **300** while maintaining the contact between the walls **212**, **310a**. As in the above example, once the actuation motion is removed, the walls **310** can return to the first wall diameter **312** position and the lateral and orbital motions can be prevented and only rotational movement can be allowed.

FIG. 4A illustrates the three elements, the valve **100**, the locator **200** and the adjustor **300** in an example. The locator **200** is centered **204** over the rotor axis **106** of the valve. Once the adjustor **300** is placed within the locator **200**, the magnetic axis **306** can then be coaxial with the center **204** of the locator **200** and the rotor axis **106** of the valve. In one example, it is only in this position, specifically when the magnetic axis **306** is coaxial with the rotor axis **106**, that the magnetic field generated by the magnets **304** is aligned to displace the rotor **104** out of the locking element **108** and into the position to be adjusted. To adjust the position of the rotor **104**, the adjustor **300** is rotated within the locator **200** and the magnets **304** move the rotor **104** to the next position. Once the adjustor **300** is removed from the locator **200**, the rotor **104** is repositioned into the locked position and restrained by the locking element **108** from any further movement.

The adjustment position described above is typically difficult to achieve on the first attempt by the user. As noted above, at least hair and swelling are reasons why the user misaligns

the locator **200** over the valve **100**. FIG. 4B illustrates an example of a misalignment. If the center **204** of the locator **200** is not aligned with the rotor axis **106**, then it is likely that the magnetic axis **306** is not coaxial with the rotor axis **106** and cannot displace the rotor **104** to permit it to be adjusted. In this situation, multiple attempts are made to position the adjustor **300** to adjust the valve **100**. In one example, there is no feedback to the user when the magnetic axis **306** is coaxial with the rotor axis **106**, thus the user can easily believe the adjustment has been made. To confirm the adjustment, the user needs a separate tool to determine the position of the rotor **104**. An indicator (not illustrated) can be used to determine the position of the rotor **104**, and if the indicator reports that the valve **100** has not been adjusted, the user must repeat the process with the locator **200** and adjustor **300**, trying to align the magnetic axis **306** with the rotor axis **106** to perform the adjustment.

Allowing the adjustor **300** to move within the locator **200** can, in one example, solve this problem. Setting the wall **310a** to the second wall diameter **316** allows the adjustor **300** to move within the locator **200**. This allows the magnetic axis **306** to move away from the misaligned center **204** of the locator **200**. This increases the chance that the magnetic axis **306** can be moved to a position coaxial with the rotor axis **106** to unlock the rotor **104**. In one example, once the rotor **104** is unlocked, moving the adjustor **300** either laterally or orbital within the locator **200** does not allow the rotor **104** to move to the locked position. Thus, the final position of the adjustor **300**, once the wall **310** is returned to the first wall diameter **312**, does not need to have the magnetic axis **306** coaxial with the rotor axis **106** to perform the adjustment.

FIGS. 5A-5C illustrate this principal graphically. FIG. 5A is the initial position of the rotor axis **106** in the valve **100**, the center **204** of the locator **200** and the magnetic axis **306** of the adjustor **300**. The rotor axis **104** is at position (4,4) and the center **204** and the magnetic axis **306** are at position (2,2). Thus, the magnetic axis **306** is not coaxial with the rotor axis **106** and the adjustment of the rotor **104** cannot be performed. FIG. 5B illustrates a position when the user has applied the actuation motion, the wall **310a** is in the second wall diameter **316** position, and is moving the adjustor **300** within the locator **200**. Line **320** illustrates a possible path the adjustor **300**, and thus the magnetic axis **306**, can take to result in the magnetic axis **306** being coaxial with the rotor axis **106**. Note that the coordinates of the center **204** (2,2) and the rotor axis **106** (4,4) did not change, just the position of the magnetic axis **306** (now (4,4)). Once the two are coaxial, the rotor **104** unlocks, and in FIG. 5C, the magnetic axis **306** can return **322** to its position concentric with the center **204**, when the wall **310** is returned to the first wall diameter **312** position. In one example, the adjustor **300** does not provide information to the user that the rotor **104** has been unlocked. It is the motion of the adjustor **300** within the locator **200** that increases the chances that the magnetic axis **306** and the rotor axis **106** align. Since the two did align, the user can now perform the adjustment and the rotor **104** can respond to the adjustor **300**. In an example, the rotor **106** only returns to the locked position once the adjustor **300** is removed from the locator **200**, the movement of the adjustor **300** within the locator **200** does not lock the rotor **104**.

FIG. 6 illustrates a flow chart of an example of this method. A user can palpate the skin **102** to locate the valve **100** (step **400**). The user can position the locator **200** over the valve **100** once located (step **402**). The position can be such that the rotor axis **106** of the valve **100** and the center **204** of the locator **200** can be either aligned or not aligned. With the locator **200** in place, the user can determine the existing

setting of the rotor **104**, with, for example, and indicator tool (not illustrated) (step **404**). The user then inserts the adjustor **300** in the locator **200** (step **406**) and performs the actuation motion (step **408**), moving the wall to the second wall diameter **316** position (step **410**). The user can then, in this example, move the adjustor **300** in the locator **200** until the magnetic axis **306** is coaxial with the rotor axis **106**, unlocking the rotor **104** (step **412**). This movement can be called “floating” the adjustor **300** within the locator **200**. The magnetic axis **306** is then moved out of alignment with the rotor axis **106** (step **414**) and the wall **310** is moved back to the first wall diameter **312** position (step **416**). The rotor **104** remains unlocked as the user adjusts the rotor **104** setting with the adjustor (step **418**), in one example, by rotating the adjustor **300**. The adjustor **300** is then removed from the locator **200** (step **420**) locking the rotor **104** into its new setting (step **422**). The user then typically confirms the new setting with the indicator tool (step **424**).

In a simplified example of the method, FIG. 7 illustrates that the user can position the locator **200** over the valve **100** (step **450**) and reduce the size of the adjustor **300** disposed in the locator (step **452**). The user can shift the location of the magnetic axis **306** until it is aligned with the rotor axis **106** of the valve, unlocking the rotor **106** for adjustment (step **454**). The magnetic axis **306** can be moved out of alignment with the rotor axis **106**, but the rotor **104** remains unlocked (step **456**). The rotor **104** can be adjusted by rotating the adjustor **300** in the locator **200** (step **458**). The rotor **104** can then be locked by removing the adjustor **300** (step **460**). In another example, discussed below and illustrated in FIGS. 10A-10D, the adjustor can be recentered within the locator using re-centering elements on the locator (step **457**).

FIG. 8 illustrates another example of a tool **500** for changing a current setting of a magnetically readable and settable valve **100** implanted in a living being. The valve **100** has an internal rotor **104** rotatable about a rotor axis **106** having a locked and an unlocked state. The tool includes a locator **600** having a center **602** aligned with the rotor axis **106** when the locator **600** is disposed over the valve **100**. In this example, the locator **600** can be a ring and does not have either a bottom or cut-out of the valve. The locator **600** can also have a first dimension **604** approximately perpendicular with the rotor axis **106**. The first dimension **604** can be a diameter of the ring **600**. A wall **606** of the ring **600** can have a second dimension **606** approximately perpendicular to the first dimension **604**. The wall **606** can form a volume in that the ring has a depth to allow an adjustor **700** to be disposed therein.

The adjustor **700** has an adjustable outer wall **702** that fits at least partially within the wall **606** of the ring **600**. The adjustor **700** has at least one magnet **704** having a magnetic axis **706**. The magnet **704** has a strong enough magnetic field to unlock the internal rotor **104**. In one example, the magnet **704** is disposed approximately in a center **708** of the adjustable outer wall **702**. The adjustable outer wall **702** has a first position dimension **710** approximately equal to or less than the first dimension **604** of the locator **600**. This sizing permits the adjustor **700** to rotate about the center **602** of the locator **600**. In an example, the only movement of the adjustor **700** permitted within the ring **600** is rotational about the center **602**, accounting for a small amount of play typical between separately formed parts.

The magnetic axis **706** can align with the center **602** of the locator **600** when the adjustor **700** is disposed within and the adjustable outer wall **702** has the first position dimension **710**. The adjustable outer wall **702** also has a second position dimension **712** less than the first dimension **604** and less than the first position dimension **710**. This sizing permits the

adjustor **700** to move more freely inside the ring **600**. The adjustor **700** can move at least lateral, rotational, and orbital in the locator **600**. This movement can misalign the magnetic axis **706** with the center **602** of the ring **600** when the adjustor **700** is disposed within and the adjustable outer wall **702** has the second position dimension **712**. When the magnetic axis **706** aligns with the rotor axis **106**, the rotors **104** move into the unlocked state and the rotation of the adjustor **700** sets the valve **100** when unlocked. The rotor **104** can return to the locked state once the adjustor **700** is removed from the locator **600**. Once the magnet **704** unlocks the rotor **104**, the magnet **704** maintains the rotor **104** in the unlocked state even when the magnetic axis **106** and rotor axis **106** are misaligned.

A plurality of indicators **608** can be disposed on the wall **606** indicating one or more valve settings. In one example, the indicators **608** can be notches or lines on the ring **600**.

A flexible element **714** can bias the adjustable outer wall **702** to one of the first position dimension **710** or the second position dimension **712**. Thus, the adjustor **700** can be in either position is its static state. The flexible element **714** can be compressed or expanded to allow the adjustable outer wall **702** to move between position dimensions **710**, **712**. The flexible element **714** can be locked in place or held under force by the user to achieve the non-static position.

All of the above dimension can be diameters.

FIG. 9 illustrates another example of a method for adjusting the magnetically adjustable valve **100** from a current setting to a target setting. The method includes positioning a locator over the valve (step **800**) and disposing the adjustor at least partially within the locator (step **802**). Permitting the adjustor to move at least two of lateral, rotational, and orbital in the locator (step **804**). This can include the step of reducing a dimension of the adjustor to less than a comparable dimension of the locator (step **806**). In other words, reducing the diameter of the adjustor in comparison to the diameter of the locator, this movement allows the adjustor to be non-concentric with the locator. During the movement, aligning the magnetic axis with the rotor axis and displacing the rotor into the unlocked state (step **808**). When the magnetic axis and the rotor axis are misaligned, the magnet is still maintaining the unlocked state (step **810**). Then, adjust the valve to the target setting (step **812**). Adjusting the valve can include expanding the dimension of the adjustor to permit the adjustor to rotate within the locator (step **814**). The valve can then be locked again by placing the valve rotor in the locked state by removing the adjustor from the locator (step **816**). Further, the adjustor can be biased to maintain one of the reduced dimension or the expanded dimension (step **818**).

Other examples of floating an adjustor within a locator are illustrated in FIGS. 10A-10D. In these examples, the locator **900** can include one or more re-centering elements **902**. In FIGS. 10A & 10B, the re-centering elements **902** are springs **902a** loading a smaller central ring **904**. The ring **904** is sized to receive a smaller sized adjustor **1000**. Smaller, in this example, can be smaller than a diameter of the adjustor but sized to fit the ring. The smaller diameter can be similar to the second wall diameter **316** noted above. When all springs **902a** are balanced, the adjustor **1000**, and its magnetic axis **1002**, can be centered in the locator **900**. However, the springs **902a** allow the ring **904**, and thus the adjustor **1000** move within the larger locator **900** to assist in aligning the magnetic axis **1002** with the rotor axis.

FIGS. 10C & 10D illustrate another example of a locator **900** with re-centering elements **902**. In this example, the re-centering elements **902** can be tactile elements **902b**. The tactile elements **902b** can be a raised or grooved surface of the locator **900**. The tactile elements **902b** are set inwards from an

11

outer wall **906** of the locator. In one example, the tactile elements **902b** are set in a circular pattern and correspond with setting positions of the valve.

Correspondingly, the adjustor **1000** can have a mating tactile surface **1004**, grooves or raised surfaces. When the tactile elements **902b** and the mating tactile surface **1004** are properly set into each other, and when the user rotates the adjustor **1000** inside of the locator **900**, there is some form of physical or auditory feedback to the user. The proper setting to receive feedback is when the adjustor **1000** is centered in the locator **900**.

In another example, the physical feedback can also be provided at the time the adjustor **1000** is centered in the locator **900**. In either example, when the adjustor **1000** is moving within the locator **900**, the user will experience either no or diminished feedback, alerting the user that the adjustor **1000** is not centered. This allows the user to float the adjustor **1000** and then recenter it to adjust the valve.

Further to the above, the tactile elements **902b** and the mating tactile surface **1004** can also be inversed, in an example. By that, the feedback delivered to the user can be experienced only when the adjustor **1000** is not centered. Once centered, no feedback is provided to the user.

While the foregoing has described what are considered to be the best mode and/or other examples, it is understood that various modifications may be made therein and that the subject matter disclosed herein may be implemented in various forms and examples, and that the teachings may be applied in numerous applications, only some of which have been described herein. It is intended by the following claims to claim any and all applications, modifications and variations that fall within the true scope of the present teachings.

We claim:

1. A tool for changing a current setting of a magnetically readable and settable valve implanted in a living being, the valve having an external cross-section and an internal rotor rotatable about a rotor axis having a locked and an unlocked state, the tool comprising:

a locator comprising:

a center aligned with the rotor axis when disposed over the valve;

a first dimension approximately perpendicular with the rotor axis; and

a wall having a second dimension approximately perpendicular to the first dimension and forming a volume; and

an adjustor disposed in the volume, comprising:

an adjustable outer wall at least partially disposed within the volume; and

a magnet unlocking the internal rotor, having a magnetic axis, and disposed approximately in a center of the adjustor;

wherein the adjustable outer wall has a first position dimension approximately equal to or less than the first dimension of the locator, permitting the adjustor to rotate about the center of the locator;

wherein the magnetic axis is aligned with the center of the locator when the adjustor is disposed in the volume and the adjustable outer wall has the first position dimension;

wherein the adjustable outer wall has a second position dimension less than the first dimension of the locator and less than the first position dimension, permitting the adjustor to move at least two of lateral, rotational, and orbital in the volume of the locator;

12

wherein the magnetic axis can be misaligned with the center of the locator when the adjustor is disposed in the volume and the adjustable outer wall has the second position dimension;

wherein the rotor is in the unlocked state when the magnetic axis aligns with the rotor axis; and

wherein the rotation of the adjustor sets the valve when the rotor is in the unlocked state.

2. The tool of claim **1**, wherein the locator further comprises:

a guide to dispose the locator over the valve; and

a plurality of indicators disposed on the wall indicating one or more valve settings.

3. The tool of claim **1**, wherein the rotor returns to the locked state once the adjustor is removed from the volume of the locator.

4. The tool of claim **1**, wherein the adjustor further comprises:

a flexible element biasing the adjustable outer wall to one of the first position dimension or the second position dimension.

5. The tool of claim **4**, wherein the flexible element is one of compressed or expanded to allow the adjustable outer wall to move to one of the second position dimension or first position dimension, respectively.

6. The tool of claim **1**, wherein once the magnet unlocks the rotor, the magnet maintains the rotor in the unlocked state when the magnetic axis and rotor axis are misaligned.

7. The tool of claim **1**, wherein the first dimension, the first position dimension, and the second position dimension are a first diameter, a first position diameter and a second position diameter, respectively.

8. A tool for changing a current setting of a magnetically readable and settable valve implanted in a living being, the valve having an external cross-section and an internal rotor rotatable about a rotor axis having a locked and an unlocked state, the tool comprising:

a locator comprising:

a center aligned with the rotor axis when disposed over the valve;

a first dimension approximately perpendicular with the rotor axis;

a wall having a second dimension approximately perpendicular to the first dimension and forming a volume; and

a re-centering element disposed in the volume; and

an adjustor disposed in the volume, comprising:

an outer wall at least partially disposed within the volume; and

a magnet unlocking the internal rotor, having a magnetic axis, and disposed approximately in a center of the adjustor;

wherein the outer wall has an adjustor dimension less than the first dimension of the locator, permitting the adjustor to move at least two of lateral, rotational, and orbital in the volume of the locator;

wherein the re-centering element is configured to center the adjustor in the locator, which is the magnetic axis aligned with the center of the locator, permitting the adjustor to rotate about the center of the locator;

wherein the magnetic axis can be misaligned with the center of the locator when the adjustor is disposed in the volume;

wherein the rotor is in the unlocked state when the magnetic axis aligns with the rotor axis; and

wherein the rotation of the adjustor sets the valve when the rotor is in the unlocked state.

13

9. The tool of claim 8, wherein the re-centering element is one of a resilient element and a ring or one or more tactile elements.

10. A method for adjusting a magnetically adjustable valve from a current setting to a target setting, the valve being implanted in a patient and the valve having an internal rotor rotatable about a rotor axis having a locked state and unlocked state, the method comprising:

placing a locator over the valve;

disposing an adjustor having a magnet with a magnetic axis at least partially within the locator;

permitting the adjustor to move at least two of lateral, rotational, and orbital in the locator;

aligning the magnetic axis with the rotor axis and displacing the rotor into the unlocked state;

maintaining the unlocked state when the magnetic axis and the rotor axis are misaligned; and

adjusting the valve to the target setting.

14

11. The method of claim 10, further comprising the step of placing the valve rotor in the locked state when removing the adjustor from the locator.

12. The method of claim 10, wherein the permitting step comprises the step of reducing a dimension of the adjustor to less than a comparable dimension of the locator.

13. The method of claim 12, wherein the adjusting step comprises the step of expanding the dimension of the adjustor to permit the adjustor to rotate within the locator.

14. The method of claim 13, further comprising the step of biasing the adjustor to maintain one of the reduced dimension or the expanded dimension.

15. The method of claim 13, further comprising the step of recentering the adjustor within the locator using a re-centering element disposed on the locator.

* * * * *